

EXHIBIT 20



April 16, 2024

Mr. Kevin Hynes
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Re: Expert Report of Matthew Sanchez PhD in the matter of *Jerry B. and Patsy Newton v. Johnson & Johnson, et al*, Dallas County, Texas, No.: DC-19-09317.

Summary

I respectfully submit this report on behalf of Johnson & Johnson. I have been asked to opine concerning the alleged contamination of asbestos in talc products manufactured by Johnson & Johnson using talc from Val Germanasca Italy, southern Vermont USA, and Guangxi China. I have reviewed the scientific literature regarding both the talc mines at issue as well as any testing on talc products manufactured by Johnson & Johnson, as well as government and private industry records relative to the testing of above products for the presence of asbestos. It is my opinion that Johnson & Johnson talcum based products do not contain asbestos.

Talc Is Not Asbestos

Talc is used in a wide variety of commercial applications, ranging from pharmaceuticals and cosmetics to ceramics, paints, paper and asphalt roofing. In its purest form, talc is a mineral and is defined as a magnesium silicate, with composition $Mg_3Si_4O_{10}(OH)_2$. The end-uses for talc are determined by variables such as bulk composition, particle size and shape, specific gravity, hardness, and color.

Asbestos

Asbestos is a collective term that describes a regulated group of six naturally occurring, highly fibrous silicate minerals that form as fiber bundles, which are easily separated into long, thin, flexible fibers when crushed. The six minerals that, when crystallized in a rare asbestiform habit, are regulated as asbestos fall into two groups of minerals: serpentine and amphibole. Talc is not one of these minerals and is not asbestos regardless of morphological habit.

Serpentine and amphibole minerals crystallize or grow in both a rare asbestiform and more common non-asbestiform habits. The asbestiform varieties of these minerals are rare and likely account for less than one percent of the known world occurrences of each mineral (Krause 1977 and Campbell et al. 1977). Serpentine and amphibole minerals with a non-asbestiform habit and resulting morphological properties are not asbestos. The table below shows the asbestiform and

non-asbestiform habit of each serpentine and amphibole mineral associated with term asbestos.”¹

Mineral Family	Asbestiform	Non-Asbestiform
Serpentine	Chrysotile	Antigorite/Lizardite
Amphibole	Crocidolite	Riebeckite
Amphibole	Amosite	Grunerite-Cummingtonite
Amphibole	Tremolite Asbestos	Tremolite
Amphibole	Anthophyllite Asbestos	Anthophyllite
Amphibole	Actinolite Asbestos	Actinolite

It is possible that talc may contain either serpentine and/or amphibole group minerals, e.g. tremolite, however, to have asbestos one must determine if the amphibole present is the asbestiform variety. The mere presence of any amphibole mineral is not the same as asbestos contamination. Analysis must determine if these minerals are in fact asbestiform and thus asbestos.

It is true that some talc deposits can contain asbestos and some asbestos deposits can contain talc; for example, talc is a common accessory mineral in some chrysotile deposits, however the specific geologic processes that control the formation of minerals of any given talc deposit are unique and control the potential for asbestos contamination in that talc ore. Thus, if the question of asbestos contamination in any talc or talc-containing product is to be answered, the source mine(s) of that talc needs to be identified and specific facts concerning that deposit and talc product derived from that deposit must be evaluated. Thus, not all talc derived from a talc source with the potential for contamination would be contaminated with asbestos.

Serpentine, amphibole, talc, or other mineral group or species, if present as elongated fragments, (whether defined by > 3:1 and > 5mm lengths or > 5:1 aspect ratio and > 0.5mm lengths) are not the same thing as a finding of asbestiform habit and resulting microscopic morphology. IARC 2010 states regarding talc and its asbestiform variety (page 279):

“Description: Commonly thin tabular crystals, up to 1 µm in width; talc is usually massive, fine-grained and compact; it also occurs as foliated or fibrous masses or in globular stellate groups. Talc particles are normally thin and plate-like, but the size of the individual plates varies among different bodies of ore. When viewed under the microscope on end, talc platelets may appear as fibres (Cralley et al., 1968). These are not true fibres and should not be confused with asbestiform talc. Asbestiform talc is formed when talc plates elongate parallel to the a axis within the plate to

¹ See 40CFR§763.83, 29CFR§1910.1001, 30CFR§56.5001, 1977 Federal Register CPSC Vol. 42, and No. 146, 1974 Federal Register US BOM Vol. 39, No. 127 part IV.

form true ribbon-like fibres of talc. These fibres may occur in an asbestiform habit consisting of bundles of narrow fibres randomly oriented around the axis of elongation (c axis)".

Thus, in order for talc to be asbestiform it has to have formed in this habit. Furthermore, IARC 2012 states (pg 221):

"The structure of silicate minerals may be fibrous or non-fibrous. The terms 'asbestos' or 'asbestiform minerals' refer only to those silicate minerals that occur in polyfilamentous bundles, and that are composed of extremely flexible fibres with a relatively small diameter and a large length. These fibre bundles have splaying ends, and the fibres are easily separated from one another (USGS, 2001; HSE, 2005)."

The only generally accepted testing methodologies to determine if a sample is composed of minerals with an asbestiform habit are those put forward and described in OSHA ID 191, EPA600/R-93/116, and ISO 22262-1. Thus, in order to have asbestiform talc, the observed talc must not simply be elongated but must meet the requirements of the asbestiform morphology. Last, IARC 2012 is clear in its warning of how these terms have been misapplied in the literature (pg 230):

"Talc containing asbestiform fibres is a term that has been used inconsistently in the literature. In some contexts, it applies to talc containing asbestiform fibres of talc or talc intergrown on a nanoscale with other minerals, usually anthophyllite. In other contexts, the term asbestiform talc has erroneously been used for talc products that contain asbestos. Similarly, the term asbestiform talc has erroneously been used for talc products that contain elongated mineral fragments that are not asbestiform. These differences in the use of the same term must be considered when evaluating the literature on talc. For a more detailed evaluation of talc not containing asbestiform fibres, refer to the previous IARC Monograph (IARC, 2010)".

Non-talc minerals do occur within talc deposits. Those minerals are often referred to as "accessory minerals" and typically include chlorite and dolomite. If asbestos were present in talc, it would be considered an accessory mineral. Several things must happen for asbestos contamination to occur in a finished talc-containing product, which I outline in general terms in the following paragraphs.

- First, asbestos must be present in the area being mined. Then, the miners must include non-talc rock with the talc as it is being mined, and this non-talc rock must contain asbestos. Talc veins are often up to several meters thick, and not all talc that is mined will contain non-talc rock; most will not.
- Second, at least some of the non-talc rock that is mined with the talc must contain asbestos.
- Third, the non-talc rock, which contains asbestos, must survive the milling processes that are designed to remove impurities from the talc. For example, hand sorting, mechanical

screening, froth flotation, and other separation (also known as “beneficiation”) techniques are used to remove impurities.

- Fourth, among the tons of product that is mined and sold to customers, the particular talc with asbestos contamination must reach a manufacturer of a talc or talc-containing product.
- Fifth, among the tons of product sold to the manufacturer, the particular talc with trace asbestos contamination must be placed into a container (one among thousands), and plaintiff must obtain that particular container.
- Sixth, this process must be repeated over and over for plaintiff to have repeated exposure to a talc or talc-containing product contaminated with asbestos.

From a mineralogical/geological perspective, even in the instances where asbestos contamination could occur, e.g. a particular mine where asbestos at times has been detected during quality assurance testing, this contamination would be a sporadic event. Thus, in order to determine if the plaintiff was exposed to asbestos contaminated talc, the actual containers of a given product would need to be tested.

Val Germanasca, Italy

I understand that Val Germanasca, Italy was a source mine used for Johnson & Johnson’s talcum powder. I have evaluated the scientific literature related to the geology of the talc formations in Val Germanasca. I have personally visited the mine and mill and conducted an evaluation, which included sampling the talc ore as well as waste rock and country rock. It is my opinion that the talc mined in Val Germanasca is not contaminated with asbestos, nor has it been contaminated in the past.

As discussed by Sandrone, et al., the Val Germanasca mine is known for “high-quality cosmetic talc.” R. Sandrone & S. Zuchetti, Geology of the Italian high-quality cosmetic talc from the Pinerolo district (Western Alps), Zuffar’ Days – Symposium (1988).

In Pooley et al. (1972), three researchers in the Department of Mineral Exploitation at University College in Cardiff, England, conducted a mineralogical evaluation of the Val Germanasca mine. The purpose of the investigation was to try to locate non-talc minerals, including asbestos that could be found together with the talc. The researchers did not find asbestos in the talc, and even certain fibrous amphibole particles found in the rocks adjacent to the talc did not display the characteristics of asbestos when examined under the electron microscope. Pooley, F.D., et al., An Examination of Italian Mine Samples and Relevant Powders (1972).

In 1976, Dr. Pooley later wrote a letter to the FDA confirming that he found no asbestos in his testing of Italian talc. March 9, 1976 Ltr. from F. D. Pooley to R. Shapiro. In its 1992 Health Assessment Document for Talc, the EPA characterized Val Germanasca talc as “very pure” and approved of Dr. Pooley’s findings. EPA Health Assessment at 3-26, 3-35. In its 2010 monograph

regarding the available mineralogical data on the asbestos content of talc, IARC likewise described the talc from Val Germanasca as “very pure” and, citing Pooley, noted that tests of this talc found no asbestos. IARC 2010 at 318. Table 1.17 shows no reports of serpentine or tremolite occurring in Italian talc. IARC 2010 at 307.

While I am not a professional epidemiologist, epidemiological studies are relevant to my opinion that the source talc mines at issue did not contain asbestos. Four epidemiological studies have followed thousands of talc miners and millers from Val Germanasca. These studies found that there were no deaths among the miners and millers as a result of mesothelioma. Rubino, et al. (1976), Rubino et al. (1979), Coggiola, et al. (2003), Pira et al. (2017), and Ciocan et al (2022). In addition there are a large number of publications which discuss the geology of the Val Germanasca region. I am not aware of any published literature in which researchers either examined the geology of the Val Germanasca region or tested samples of talc from the mine and reported that the talc contains any asbestos.

I visited the current mining and milling operations at Val Germanasca from November 9 to November 12, 2015 (report dated March 24, 2016). The focus of my visit was to (1) obtain samples from both the mining and milling operations that are representative of the current mining operation, (2) assess the current talc ore and surrounding country rock for asbestos mineralization, and (3) understand the mine’s current and past programs as they relate to asbestos testing to ensure product quality. I took a total of twenty (20) samples during the site visit, which represented the talc ore, non-talc waste rock (both siliceous and carbonaceous lenticular inclusions were sampled), milled product, country rock where amphiboles were observed, and talc from both French and Chinese sources that are also milled at the Malanaggio plant. The samples were analyzed by XRD, PLM, and TEM. In no sample were chrysotile or asbestosiform amphiboles observed.

Southern Vermont Talc

I understand that Johnson & Johnson used the Hammondsville, Argonaut, and Rainbow mines and potentially other mines in southern Vermont as source mines used for Johnson & Johnson’s talcum powder. I have evaluated the scientific literature related to the geology of the talc formations in southern Vermont. It is my opinion that the talc mined in southern Vermont is not contaminated with asbestos, nor has it been contaminated in the past.

The development of plate tectonics last century was a unifying theory in geology. Briefly, the theory states that the earth’s crust is composed of several large plates that move with respect to one another. When the plates separate, oceans form (e.g., the Atlantic Ocean) and when they collide, mountain chains are built (e.g., the Alps). Another important point is that the continental plates are lighter than ocean plates; thus, when the two collide, the ocean plate is “subducted” below the continental plate.

Currently, the east coast of North America is not geologically active; however, this was not the case in the geologic past. Over the past 600 million years this region has undergone geological development favorable to talc formation mainly by occurring at a convergent and divergent plate boundary. This caused Vermont's geology to be composed of differing rock types trending in a more or less north-south direction that formed as a result of a converging plate boundary (Van Diver, 1987 and Doolan, 1996). As these geological processes occurred ocean sediments were changed by heat and pressure into a metamorphic rock type called schist when ancestral North America collided with ancestral Africa. Next, these rocks were uplifted forming the Appalachian Mountains. During this process portions of them were also altered into a rock type known as serpentinite, and in local areas, the serpentinite was further altered to talc. Serpentinite gains its name from the fact it is composed predominantly of serpentine group minerals (all with the composition of $Mg_3Si_2O_5(OH)_4$) of which there are three: antigorite, lizardite, and chrysotile, with only the latter being an asbestos mineral.

Talc ($Mg_3Si_4O_{10}(OH)_2$) forms from alteration of other minerals. The southern Vermont talc deposits form as lower pressure and temperature metasomatic induced reactions between serpentinite and the silica rich country rock. McCarthy et al. (Table 1, 2006) noted that Vermont talc contained trace amounts of serpentine and no tremolite. Van Gosen et al. (2004) also gives a summary of talc formation and likewise points out that amphiboles only occur at higher temperatures of formation.

Even though Van Gosen et al. (2004) notes the lack of amphiboles in Vermont-style talc deposits, some clarification of his section on "Vermont talc" is needed regarding both amphibole and asbestos content of Vermont talc. He cites a paper by Zodac (1940) which notes fibrous actinolite occurs in the blackwall at the former Chester, Vermont talc deposit located in Windsor County. However, Zodac is quoted as saying the material is "needle-like;" this would preclude it being a morphological fiber of asbestos. Regardless, all of the discussion in Veblen and Burnham (1978a, 1978b) are from samples removed from the blackwall and not the talc ore itself. In the last sentence of the Vermont talc section, Van Gosen et al. state fibrous amphiboles are in the blackwall at Chester, and cite Veblen and Burnham (1978b). However, Veblen and Burnham (1978b) never mention fibrous amphiboles, but fibrous biopyribolites instead. Thus, the sentence in Van Gosen et al. (2004) should be rewritten to read: "These newly found biopyribolites represent intermediate products of incomplete reactions during the conversion of anthophyllite and cummingtonite to talc." Van Gosen has, in fact, acknowledged this rewording would be more accurate (Van Gosen personal communication). As noted above, the Chester deposit was in Windsor County, as is the former Frostbite mine. Robinson (et al. 2006) discuss the geology of the Frostbite mine and make no mention of asbestos minerals occurring in the deposit, although they note the as-expected occurrence of antigorite, a serpentine-group mineral.

To further understand the potential for Vermont talc in general and southern Vermont talc in particular to contain asbestos: 1) published literature outside of geology was sought and 2) samples of southern Vermont talc ore and Johnson & Johnson products were obtained and

characterized. Along with the geological studies noted above workers in the health-related fields became interested in Vermont talc as a method to ascertain the health effects of talc not contaminated with asbestos. McCrone (1977) undertook a study of 100 samples, with 23 from Vermont and found no asbestos in any of the Vermont samples. Boundy et al. (1979) also collected samples and found no asbestos in any samples from three operating talc mines in Vermont. Dr. Gunter obtained seven samples of talc from the Argonaut Mine and Buzon (2016) determined, by X-ray powder diffraction, that all seven were asbestos free.

I was provided hundreds of internal documents from Johnson & Johnson from the different mines and mills in southern Vermont. The clear majority of these reports and testing documents found talc ore and products from this mining district to be asbestos-free. These testing results include XRD, PLM, and TEM reports from multiple independent laboratories starting in the early 1970s. However, out of the hundreds of tests performed there are some testing documents that did at first mention observing chrysotile in trace quantities, but follow-up analysis of the same samples found them to be asbestos free. There were several reasons for this, but mainly lab contamination was cited. I was aware of the testing work by Lewin as I had reviewed it earlier. Even in my earlier review, I questioned his results. In the documents provided by Johnson & Johnson, I discovered my skepticism to be correct as they had hired some of the most competent mineralogists in the world to review his work. As expected, they found considerable scientific inaccuracies with it. Finally, there was the occasional report of non-asbestiform tremolite/actinolite, but never any reports of anthophyllite.

Dr. Fred Pooley also performed an evaluation in Vermont and collected samples from both the ore footwall and hangingwall in order to characterize the minerals that would be possible contaminants of the talc ore. No asbestos was observed. In regard to amphibole and serpentine minerals he concluded:

"The amphibole minerals were found in discrete locations and not disseminated throughout the talc ore and were not asbestiform in character. Serpentine mineral was found in the specimens located at the centre of the orebody but no fibrous components were observed."

Based on the past geological investigations, the geological development of the southern Vermont talc deposit, and past peer-reviewed/refereed publications, it is my opinion to a reasonable degree of scientific certainty that it appears very unlikely that asbestos occurred in these talc deposits, or in turn in products produced from them. It is also worth pointing out that many of the past testing documents need to be critically evaluated in light of the above and not taken at face value. Most certainly serpentine group minerals do occur in these deposits, but investigators mostly only reported finding the antigorite variety, as geological conditions did not favor the formation of chrysotile. The occurrence of amphiboles appears rare in the deposit, and there is no evidence that any amphiboles in the deposit, or the schist enclosing it, are asbestiform.

To further summarize, this talc deposit formed by low-temperature alteration of serpentinite, a geological condition not favorable for the formation of asbestos, but where non-asbestiform serpentine occurs. Several published studies found no asbestos in talc produced in this mining district (Blount, 1991; Boundy et al., 1979; McCrone, 1977), while to my knowledge no published study found asbestos. In fact, Vermont talc was chosen by Boundy et al. (1979) to determine the health effects to miners and millers exposure to asbestos-free talc. IARC (2010) and McCarthy et al. (2006) report no asbestos in Vermont talc.

Lastly, I have conducted testing on 15 samples collected from the Argonaut Mine collected by Professor Mickey Gunter (Sanchez report dated April 6, 2018 "Analytical Test Report of the Gunter Argonaut Samples"). No asbestos was observed in any of the talc samples. In two non-talc samples composed of primarily serpentine group minerals a trace quantity of chrysotile was observed by TEM. No asbestiform amphiboles were observed in any sample. Non-asbestiform tremolite-actinolite amphibole was the primary component of one sample, which is also not a talc sample.

Guangxi, China Talc

I understand that Guangxi, China is a source mine used for Johnson & Johnson's talcum powder. I have evaluated the scientific literature related to the geology of the talc formations in Guangxi, China. It is my opinion that the talc mined in Guangxi, China is not contaminated with asbestos, nor has it been contaminated in the past.

There are at least three major talc mining regions in China: Liaoning, Guangxi, and Shandong, in order of volume of talc produced. Each of these regions are geologically unique. Johnson & Johnson sources their talc from the Guangxi Province talcs. The talc mines are located in the mountainous regions west of Guilin City in the northern part of the Province. The geology of northern Guangxi is complex. The respective mines are located in the Danzhou Formation which is equivalent with the Banxi formation in Hunan and the Dengshan Group in Jiangxi province. These sedimentary formations were deposited in the Mesoproterozoic and deposited in a rift related basin (Wang and Li 2003). These sedimentary groups were subsequently metamorphosed to low-grade green-schist facies assemblage and folded during the Jiangnan Orogeny in the Neoproterozoic (Wang et al. 2006), and likely uplifted during the Mesozoic. The mountainous region that trends northeast and southwest to the west of the city of Guilin is also referred to as the Jiangnan old land (Yan et al. 2003). These metamorphosed sedimentary formations consist of primarily siliceous sediments composed of pelitic schists, phyllites, slates, siltstones, sandstones, conglomerates (Li, X.H. 1999), and sequences of carbonate bearing rocks (Wang and Li 2003). These carbonate rock sequences are likely the protolith for the talc bearing zones that compose the Guangxi China talc deposits.

Observed country rock (i.e. non-talc ore) in contact with the talc ore consists of quartzite and phyllitic slates. Within the mining area are veins of non-talc rocks composed of grey carbonates

(primarily dolomite) and some veining of hydrothermal quartz. They do not exhibit any fibrous mineralization. The country and non-talc rocks are removed from the talc ore prior to milling during the various stages by hand sorting. The sorting is done based on the distinct color differences between the non-talc rock and talc ore.

The talc bearing zones and talc ore consist of pale green to white and grey colored bands; the talc is the primary component of the pale green to white bands while carbonate minerals are the primary component in the grey bands.

Mining is accomplished by open pit methods and the talc ore is initially sorted at the mine prior to transportation off-site. The talc is initially screened, washed, and hand sorted based on coloration of the ore. The pale green to white ore constitutes nearly pure talc and the more grey carbonate-rich rock is either wasted or sorted into separate production lines at the mine and plant sites. The talc ore from the Guiguang mine is transported to Guilin for further beneficiation, transportation as lump talc, or milled and packaged.

Sorting of the talc from non-talc rock is primarily done by hand, this means that workers physically separate the talc from non-talc rocks. For larger rocks, they are either separated as lump talc or where they are impure, pneumatic hammers are used to break the rocks into manageable pieces for further beneficiation.

Quality Control (QC) testing of the milled talc on site is done on a routine basis. The testing involves sieving, whiteness testing, density testing, X-ray Fluorescence, wet chemistry for heavy metals, and powder X-ray diffraction (XRD). The testing conducted is in accordance with the Chinese Pharmacopeia. With regard to asbestos, XRD is used to screen for the presence of the potentially asbestos minerals serpentine and amphibole. The test method being employed is the Chinese Pharmacopeia standard GB/T15344-2012 “Methods of the Physical Test of Talc” and which the QC technicians use to screen for asbestos. Microbial testing is also performed for food and cosmetic grades of talc.

The analytical testing conducted is composed of a combination of powder X-ray diffraction (XRD), polarized light microscopy (PLM) –generally in accordance with the current United States Pharmacopeia (USP) or CTFA J4-1, and transmission electron microscopy (TEM).

In 2009, the FDA conducted off-the-shelf product sampling of cosmetic talcum powders as well as solicited USP grade talcs from talc mining and trading companies. At that time, three grades of pharmaceutical talc labeled Imperial 200, 250, and 400 USP were known to come from Guangxi. A contract laboratory on the FDA’s behalf conducted the testing and they performed PLM and TEM testing. No asbestos was detected in the three USP grade talcs submitted. In addition to these Guangxi source talcs they also tested a sample of Johnson’s Baby Powder with the result of no asbestos detected. This is relevant as Guangxi talc was the source of Johnson’s Baby Powder during this time period.

Starting in 2009, RJ Lee Group, Inc. has conducted both talc surveys and quarterly monitoring for Johnson & Johnson of Guangxi-sourced talcs. The testing incorporated the current USP talc monograph with PLM and TEM testing of each sample submitted. Results of these analyses showed no serpentine or amphibole group minerals were detected, let alone chrysotile and/or amphibole asbestos.

Additional mineralogical based testing on Guangxi-sourced talc were performed by Buzon in 2016 wherein she examined seven specimens by XRD and found no serpentine or amphibole minerals present.

Early in 2019 I undertook additional analyses of current Johnson & Johnson talc products purchased in California. A total of 12 samples were tested by XRD, PLM, and TEM methodologies. No asbestos was observed in any of the 12 bottles. Additionally, I analyzed another 10 samples of Johnson & Johnson talc products in the Shawn and Holly Johnson v. Johnson & Johnson, et al matter filed in California. No asbestos was observed in any of those 10 bottles.

Product formulation

My opinion that Johnson & Johnson talcum powder did not contain asbestos is also based upon my review of internal Johnson & Johnson documentation requiring that only talc free of asbestos be used in Johnson & Johnson's talcum powder. I have reviewed Johnson & Johnson's Raw Material Purchase Specifications, which confirm that suppliers were required to analyze each shipment of talc for asbestos content and certify that each shipment of talc was asbestos free.

Product testing record

My opinion that Johnson & Johnson's talcum powder did not contain asbestos is based on a decades-long testing record, including historical testing by Johnson & Johnson and its suppliers, independent, third-party testing, and historical government testing. Review of the entire testing record leads me to conclude Johnson & Johnson's talcum powder did not contain asbestos.

Historical testing by Johnson & Johnson and its suppliers

I have reviewed documentation regarding Johnson & Johnson's testing protocols for its talc supply. My understanding is in the early 1970s, Johnson & Johnson developed a state-of-the-art, reliable testing method and internally tested its talc supply, along with talcs never intended to be used in finished Johnson & Johnson talcum powder products, for the presence of asbestos using several different testing methods. This was a response to false alarms raising the issue of possible contamination of cosmetic talc with asbestos. *CTFA-FDA Scientific Liaison Report*, CTFA Cosmetic Journal, Vol. 3, No. 4 (1971). Johnson & Johnson's policy required it to discard any talc lot that was sampled and determined to be contaminated with asbestos. I have reviewed Johnson

& Johnson's internal testing results from the relevant time periods and confirmed that the overwhelming majority of these results were negative for amphibole or serpentine minerals.

Independent, third party testing

I have reviewed numerous independent testing results submitted by McCrone Laboratories, RJ Lee Group, and other third-party testers comprising test results covering Johnson & Johnson's talcum powder for the past 40+ years. These test results show that these experts have consistently determined that Johnson & Johnson's talcum powder was not contaminated with asbestos. These testing results are consistent with the bulk of reported studies and testing by the government, academics, and other laboratories.

In addition to these tests, RJ Lee Group has recently completed sixteen (16) samples as part of the MDL process. The testing conducted was in accordance with generally accepted methods and found non-asbestiform amphibole in each of the 16 samples. The amphibole identified in fifteen (15) of the samples is cummingtonite with clear indications of talc alteration and tremolite in one (1) sample. These findings of cummingtonite are consistent with another bottle tested in March 2018 of a "museum" specimen from 1978 wherein non-asbestiform cummingtonite was observed. For these same 17 samples both Dr. Longo (one sample) and Mr. Poye (8/16 samples) misidentified the amphibole present as anthophyllite asbestos. Thus, they misidentified both the habit of the amphibole and the species of amphibole. These mistakes are a result of not following generally accepted methodologies for the testing of talc for asbestos.

Twenty-three (23) additional reports from the MDL process were reported on December 12th, 27th, and 31st, 2018. Non-asbestiform amphiboles were observed in numerous of these samples. Depending on the specific samples the amphibole types observed were tremolite and cummingtonite. In addition to these phases on three samples intergrowths of anthophyllite and the pyroboles jimthompsonite and clinojimthompsonite were observed. In one sample the suspected amphibole particles observed by PLM were intergrowths of talc and clinojimthompsonite with no observed amphibole component by TEM-SAED analysis.

In addition to the above sixteen samples RJ Lee Group has recently completed an additional ten (10) samples and seven (7) samples that are from Asia obtained through the MDL process. In none of these 17 samples were any asbestiform minerals detected. In regard to the 10 samples, non-asbestos amphibole was observed in seven of the samples. These amphiboles were mixtures of cummingtonite and tremolite. For the seven Asian samples six of the seven samples contained non-asbestiform tremolite.

RJ Lee Group has completed testing of two (2) additional samples from the Philippines market, one of which would likely be Korean sourced talc and obtained through the MDL process. Trace non-asbestiform tremolite was observed in one of the samples that based on year of manufacture would have contained Korean talc. The latter sample was from the 1990s and is

likely Chinese source and no asbestos or amphibole mineral were observed. In neither sample were any asbestiform minerals detected.

In further testing in June 2019, RJ Lee Group tested fifteen (15) samples identified as Imerys railcar samples obtained through the MDL process. No asbestiform minerals were observed in any of these fifteen samples. Non-asbestos cummingtonite was observed in five samples. Non-asbestos tremolite was observed in two samples. Non-asbestos or platy serpentine was observed in one sample.

In May of 2023, I tested a single bottle of Johnson & Johnson Baby Powder that was also tested by Dr. Longo. No asbestos was detected in the testing. Further, no amphibole or serpentine minerals were detected.

In February 2024, I tested a single split of material from MAS simply identified as M71740-001. No asbestos was detected. My report on this testing is dated February 12, 2024.

I have also reviewed the Blount 1991 article wherein Sample I was reported to contain amphibole asbestos. As I have previously testified, Dr. Blount's methodology is based on sound mineralogical principles and does allow the determination of whether an amphibole is asbestiform and thus asbestos (unlike the methods of plaintiff's experts in this case). Thus, I agree that for Sample I asbestos was observed and reported. However, the issue is the identity of Sample I. I have reviewed Dr. Blount's depositional testimony from April 2018, wherein she alleges that Sample I was Johnson Baby Powder, and then produced the bottle at the same deposition. However, Dr. Blount testified that the bottle produced and identified as Sample I was purchased in New Jersey after 1991 just prior to her moving to Vermont ca. 1996. Furthermore, Dr. Blount prior to her April deposition sent to Dr. Mickey Gunter what she represented as the samples in her 1991 article. The bag labeled Sample I contained three vials, one of which had the date 1976 written on it. Unfortunately, due to this confusion of fact I am unable to verify what the identity of Sample I is at this time. I am aware that Dr. Blount would not let the parties test this sample. Lastly, none of the other samples have been made available to me in order to test.

Historical government testing

In addition to the independent testing performed by McCrone Laboratories, RJ Lee Group, and others, historical testing by the FDA found no asbestos in Johnson & Johnson's talcum powder. In 1973, the FDA commissioned a study in which 195 products described as "Cosmetic talcum-type powders" were tested for possible asbestos contamination. As part of that study, eleven samples of Johnson & Johnson's talcum powder products were tested. Prof. Lewin did not find any asbestos in nine of the samples. As for the remaining two samples, the report concluded that one sample had inconclusive results for chrysotile and another sample contained trace amounts of tremolite. See Prof. Seymour Lewin, Final Report: Determination of Asbestos Contents of Commercial Talcum Powders (July 10, 1973).

The FDA hired DCST to verify Prof. Lewin's XRD results by analyzing the same samples with both light microscopy and differential thermal analysis. After testing Johnson & Johnson's samples (including the two implicated in Prof. Lewin's final report), the FDA concluded that both samples did not have any detectable levels of chrysotile or tremolite. See Heinz Eiermann, Tabulated Results of DCST's Analyses for Asbestos Minerals in Prof. Lewin's Study (Jan. 7, 1976).

In July 1986, the FDA responded to a November 1983 citizen's petition seeking "labeling of warning of hazardous effects produced by asbestos in cosmetic talc." The FDA's response found there was no basis at that time for the agency to conclude there is a health hazard attributable to asbestos in cosmetic talc and, without such evidence there was no need for a warning label. See 1986 Citizen's Petition Response. Even more recently, the FDA published a study conducted in 2009 and 2010 of 27 samples of cosmetic-grade raw talc and 34 samples of cosmetic products containing talc, finding no asbestos in all samples—including Johnson & Johnson's talcum powder. FDA, "Ingredients>Talc," available online at <http://www.fda.gov/cosmetics/productsingredients/ingredients/ucm293184.htm> (last visited November 13, 2019).

In October of 2019, the FDA, using AMA (the same testing laboratory as 2009-10), reported finding chrysotile by TEM analysis in two of three splits drawn from a bottle of Johnson & Johnson Baby Powder Lot #22318RB. Johnson & Johnson recalled this specific lot as it investigated this claim. Both RJLG and Bureau Veritas tested, on behalf of Johnson & Johnson, additional talcum powder samples related to this lot. The analytical testing methodology of the three laboratories was similar. Furthermore, the analytical sensitivity for both RJLG and Bureau Veritas testing was greater than that of AMA.

In AMA's report, they had analyzed Lot #22318RB in triplicate using PLM NY ELAP 198.6 and a modified TEM NY ELAP 198.4. During the TEM analysis, they reported data from three of the observed chrysotile structures. The first structure, "308006-6A Chrysotile Structure 1", appears to be consistent with chrysotile based on the EDS and SAED provided. The next two structures, "308006-6B Chrysotile Structure 1a-c" and "308006-6B Chrysotile Structure 2", do not appear to be chrysotile from the SAED provided by AMA. The first structure "308006-6B Chrysotile Structure 1a-c" does not have an observed diffraction pattern. This could indicate that this structure is a) not chrysotile, or b) the fiber was not stable during observation with the TEM. From the image provided of this structure, there appears to be no hollow tube in the center of the structure as would typically be observed in chrysotile. This structure is inconclusive at best and further data would have to be collected in order to confirm the identification as chrysotile. The third structure "308006-6B Chrysotile Structure 2" does not appear to be chrysotile from the provided SAED. The streaking in the [110] gap is reversed from what it should be. Therefore, AMA can only definitively state that one chrysotile fiber was observed during their analysis.

With regard to the control samples and blank samples reported by AMA, there are discrepancies of the dates of preparation of the unknown Johnson & Johnson sample and the dates of the provided data. For example, in the report it is stated that a 10% chrysotile spiked talc was prepared at the same time as the unknown sample. However, the data produced for the 10% spiked sample was prepared at a later date. Further, these 10% chrysotile spiked samples are prepared per batch. Also, the blank samples produced represent a different time period of preparation other than that of the Johnson & Johnson sample subsamples. Since the blank data presented is not that described in the report and, based on the fact that it is not from the same time frame, it is not representative of the environment where the Johnson & Johnson samples were prepared and analyzed. The chronology for preparation and analyses are as follows:

- August 30, 2019 samples 308006-6, 308006-6a, 308006-6b are prepared.
- September 3, 2029 sample 308006-6 analyzed.
- September 5, 2019 blank samples NB19-645, NB19-646, and NB19-647 are prepared.
- September 5, 2019 10% reference control chrysotile spike prepared.
- September 7, 2019 samples 308006-6a, 308006-6b are analyzed.
- September 18, 2019 samples NB19-645, NB19-646, and NB19-647 are analyzed.
- September 18, 2019 10% reference control chrysotile spike analyzed.
- No dates given for EB-54155 described as a carbon coating filter blank.

Furthermore, blanks samples do not encapsulate every potential for contamination. For instance, if the contamination is due to an unclean or partially cleaned pair of tweezers, and if those tweezers, while contaminated, did not handle the blank filter because it was prepared either at a different time or on a separate day, then no transfer of particulate would have been possible, thus no chrysotile observed in the blank sample. Another example described by AMA is the fact that multiple times a year they document asbestos contamination in samples from routine laboratory practice. This is in no way meant as a crimination of the AMA laboratory; it is a fact that in an asbestos testing laboratory, contamination is always a possibility and does happen.

With respect to RJLG testing, each sample or replicate of a sample was analyzed by XRD, PLM and TEM. Two splits were obtained from the original sample provided to AMA, one split labeled "blinded" and the other labeled "original". The analysis of the "blinded" sample was replicated three times, and the analysis of the "original" was replicated twenty times. RJLG was not able to duplicate the findings of chrysotile in the same bottle. These reports are dated October 28, 2019 (the original triplicate analysis) and November 5, 2019 (the additional 17 analyses of the "original" sample). Five samples (four milled talc and one baby powder) provided by Johnson & Johnson were analyzed in triplicate from the same lot that AMA tested. These samples were reported on October 28, 2019 and no asbestos was detected in any of the replicates². RJLG

² See RJLG Incident report 10\28\2019: "During the analyses of several samples by transmission electron microscopy (TEM), it was observed that some of the samples that were prepared in one room (room 107I) were found to contain

received and tested six additional lots of talc provided by Johnson & Johnson, wherein no asbestos was detected in any of those lots. The results of these tests were reported on October 29, 2019. In all, 41 tests were performed; no asbestos, amphibole, or serpentine minerals were observed in any of the tested material.

Regarding the Bureau Veritas testing, the preliminary report dated October 27, 2019 showed no asbestos observed on three replicates of the sample lot tested by AMA. The final report, dated November 27, 2019, included the preliminary report data plus additional analysis of four other samples. These are the same samples analyzed by RJLG in the October 28, 2019 report. Bureau Veritas tested each sample in triplicate by four different methods which include PLM 400 point count, PLM 1000 point count, TEM ASTM 5756, and TEM EPA/600/R-93/116. During the analysis of lot #H06228-D7(A1910246-001C and -00D) using TEM ASTM 5756, fibers were observed but Bureau Veritas determined that these structures were sepiolite rather than chrysotile. Further discussion of sepiolite and chrysotile follows. Upon review of the data provided in their report, I agree with this conclusion that these fibers are not chrysotile. Additionally, they observed two possible amphibole structures on H06228-D7 (A1910246-001C). Based on the data provided, I cannot independently verify whether or not these particles are amphibole.

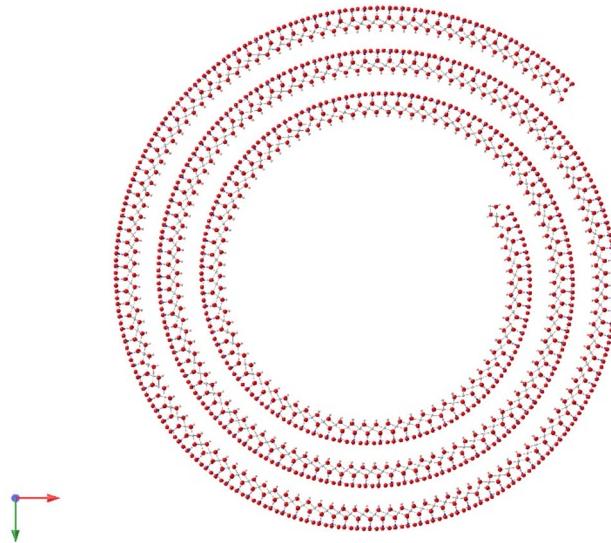
Between RJ Lee Group and Bureau Veritas, a total of 155 independent tests were conducted, 74 of which were TEM tests. In none of these tests could the presence of chrysotile be confirmed. Thus, the observation of chrysotile by AMA is most likely the result of contamination during sample handling and not from the material itself.

I reserve my right to offer opinions as more information is made available about this event.

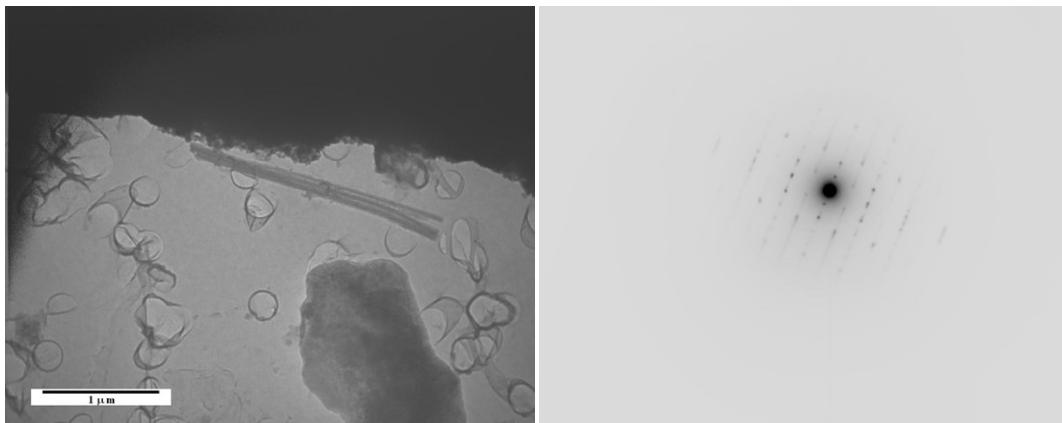
Much has been written on the mineralogy of chrysotile as it formerly had a very significant role in many industrial processes and products (See Deer et al. 2009, Ledoux 1979, and references therein). The general structure of chrysotile consists of a 1:1 layer silicate composed of a sheet of tetrahedrally coordinated silicon and a sheet of octahedrally coordinated magnesium. Because of the mismatch between the optimum bond length between the apical oxygens of the tetrahedral sheet and the octahedral sheet, the stresses created are compensated for by bending of the sheets. As the sheet extends, this curvature results in the formation of a scrolled structure around the crystallographic axis in chrysotile (see image below). The composition of chrysotile is ideally $Mg_3Si_2O_5(OH)_4$ but small amounts of other elements can substitute for magnesium in the octahedral sites (e.g. iron, nickel, manganese). Chrysotile occurs in serpentinite rocks found in

trace levels of chrysotile. Duplicate and triplicate testing of the same sample, prepared in our standard preparation room (room 122), did not contain any asbestos. Repeat testing of all samples, prepared in triplicate in our standard preparation room, indicated the samples did not contain any asbestos. Based on these results, it was concluded that some of the samples prepared in room 107I were somehow contaminated by the environment". Of the 52 total tests in the known clean environment, no sample tested positive for asbestos. Meanwhile, of the 7 tests from the known contaminated environment, 3 showed positive for chrysotile.

ophiolite sequences. The scrolled structure of chrysotile is a characteristic feature of the mineral and is exhibited by the morphology and electron diffraction patterns observed in the TEM.



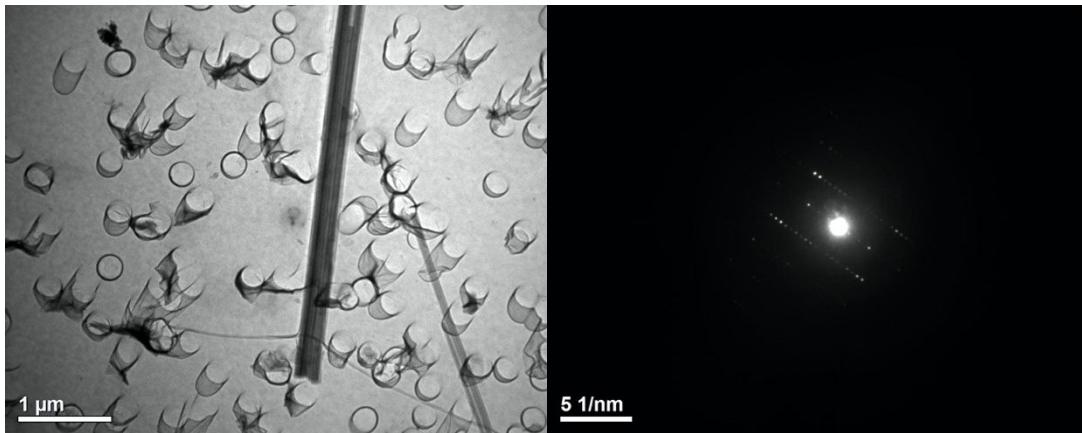
Simulated chrysotile scroll.



TEM electron micrographs of chrysotile bundle (left) and the observed SAED pattern (right). Note the distinct streaking of the SAED caused by the scrolling structure of chrysotile. Also, on the image one can observe the hollow tube running down the center of the fiber represented by a lighter grey region in the center of the fiber.

Sepiolite is a 2:1 sheet silicate clay mineral with the ideal composition of $\text{Si}_{12}\text{Mg}_8\text{O}_{30}(\text{OH})_4(\text{OH}_2)_4 \cdot 8\text{H}_2\text{O}$. Sepiolite is included as a sheet silicate as the structure contains a two-dimensional sheet composed of T_2O_5 ($\text{T}=\text{Si, Al, etc.}$), however, sepiolite does not contain a continuous octahedral sheet. This results in a ribbon structure composed of 2:1 layer silicate sheets. These ribbons are joined by apical oxygens of adjacent tetrahedral ribbons where the adjacent tetrahedral ribbons have alternating directions of the apical oxygens (see Jones & Galan 1988, and reference therein, for discussion). The arrangement of these ribbons creates a large

channel in the structure capable of weakly holding water as well as other cations. This ribbon structure causes sepiolite to form typically in a fibrous habit. Sepiolite occurs in a wide variety of environments, but seldom in significant abundance (Jones & Galan 1988). Electron microscopy of sepiolite is difficult as the structure degrades quickly as a result of dehydration of the structure in the vacuum of the electron microscope.



TEM electron micrographs of a sepiolite fiber (top) and SAED (bottom). Notice the lack of streaking within the SAED pattern.

1970s Testing

I am aware of historic testing that took place in the 1970s, including testing in 1972 by Professor Lewin at NYU and in 1976 by Drs. Rohl and Langer. It is important to note that it would be improper to rely solely on Dr. Lewin's preliminary results. Dr. Lewin's preliminary results have been described by McCrone as "grossly wrong" and by NIOSH as "erroneous." Walter C. McCrone, *The Asbestos Particle Atlas* (1980) at 3-4; NIOSH, *Analysis of Talc by X-Ray Diffraction and Polarized Microscopy* 34 (May 1977) at iii.

Likewise, Drs. Rohl and Langer's 1976 article has been discredited because it did not reliably identify asbestos. On the face of their article, Rohl and Langer stated that their methodology did not distinguish between asbestos and non-asbestos. They defined "asbestiform" as "formed like or resembling asbestos." based solely on a 3:1 aspect ratio.

Academic, private, and government scientists, including IARC, the U.S. Bureau of Mines, and the McCrone Institute, are in agreement that Drs. Rohl and Langer's 1976 report is unreliable (IARC 2010) wherein they state that "criticisms [of Rohl et al. 1976] were reasonable and little reliance can be placed on the reported concentration of tremolite or anthophyllite. The Working Group also noted that Rohl et al. (1976) stated that their methodology did not distinguish between asbestos and non-asbestiform mineral fragments." A same problem was noted by Campbell et al. 1977 wherein they state that: "In many instances, cleavage fragments of common amphibole minerals have been mistakenly identified as microscopic fibers of the related asbestiform variety.

Such lack of precision in identifying these particulates is a handicap to scientific decision making". Walter McCrone (1980) commented on the use of a 3:1 aspect ratio and its use in asbestos analysis in talc as "silly". Lastly, Krause (1977b) states in regard to the work by Rohl et al. "conclusions drawn are without scientific basis and are therefore misleading and invalid".

Indeed, for these reasons, in its 1986 review of whether cosmetic talcum powder should be affixed with a warning label, the FDA rejected this testing:

"During the early 1970s, FDA became concerned about the possibility that cosmetic talc did contain significant amounts of this material. The agency received several reports about such contamination. However, at that time, the analytical procedures for determining asbestos in talc were not fully developed, and most of the analytical work was conducted without scientific agreement as to which methods were well-suited for the identification of asbestos minerals in talc. Consequently, FDA considered all analytical results to be of questionable reliability. This assessment proved to be correct because many questions were subsequently raised about results reported in the literature in the early 1970s (see enclosed copy of National Bureau of Standards Special Publication 506 entitled "Misidentification of Asbestos in Talc.")"

1986 Citizen's Petition Response at FDA00003601.

Plaintiff Expert Testing

MVA Scientific Consultants

I have reviewed the August 1, 2017 and April 23, 2018 reports of Plaintiffs' testing expert Dr. Compton of MVA Scientific Consultants. It is my opinion that MVA's testing methods are not adequate to reliably identify amphibole minerals in an electron microscope, and where amphiboles are observed they do not differentiate between the asbestos and non-asbestos habits of these same minerals. Thus, MVA cannot reliably report the identification or quantification of asbestos in talc derived from the mines in Val Germanasca Italy.

From the as received photographs of the splits from Bureau Veritas of these samples it is clear that the vast majority of the samples were rock samples. This means that important mineralogical and sample characteristics were simply ignored during the analysis, the most important of which was the examination of mineral crystallization. This is the key feature in determining if asbestos minerals are indeed present. Furthermore, MVA had every opportunity to perform both powder X-ray diffraction and polarized light microscopy on these samples and chose to simply perform TEM analysis following an air methodology where the data is the most difficult to interpret objectively.

MVA selected the ISO 10312 method, which is equivalent to ASTM D6281 for their bulk testing by AEM. As stated above this methodology is designed by ambient air measurements and not for bulk sample analysis. ISO 22262 is the bulk sampling methodology, which is based in polarized light microscopy techniques and requires the same standard to identify asbestos as the EPA 600/R-93/116 method. The ASTM D6281 method states that the analyst must evaluate three components of each particle: “the morphology, the ED pattern, and the qualitative and quantitative EDXA” in order to determine whether that particle is or is not asbestos. ASTM D6281 ¶ 4.2. As set forth below, MVA did not meet their methods’ requirements for each of these three types of AEM analyses—morphology, the ED³ pattern, and quantitative EDXA⁴—as applied to analysis of bulk samples whether talc or other matrix.

Morphology. The ASTM D6281 method defines a “fiber” as “an elongated particle that has parallel or stepped sides.” ASTM D6281 ¶ 3.2.22. Several of the particles MVA identified as “fibers” do not meet this definition because they are not parallel and/or do not have stepped sides. For example, MVA identified the particles in the images below as asbestos “fibers,” but none has parallel or stepped sides:



August 1, 2017 report sample 11730AB1535 Stru_002, Str_007, and Str_010. ASTM D6281 also requires that, for fibers with stepped sides, aspect ratio be calculated by using a “width equal to the average of the minimum and maximum widths.” ASTM D6281 ¶ A3.2.1.1. There are numerous instances where MVA failed to follow this morphological requirement resulting in erroneous aspect ratios for observed particles.

For those particles that MVA correctly identified as “fibers” under their cited method, it is important to note that “fibers” are not necessarily equal to asbestos. Yet MVA equated “fibers” with “asbestos” and thus reported detecting “asbestos” in these samples because the definition of “fiber” in MVA’s chosen method (an elongated particle, with parallel or stepped sides and at least a 5:1 aspect ratio) includes non-asbestiform cleavage fragments. Indeed, as ASTM D6281 recognizes, the “test method cannot always discriminate between individual fibers of the

³ ED stands for “electron diffraction,” ASTM D6281-09 ¶ 3.4, which is equivalent to the SAED (selected area electron diffraction) analysis discussed above.

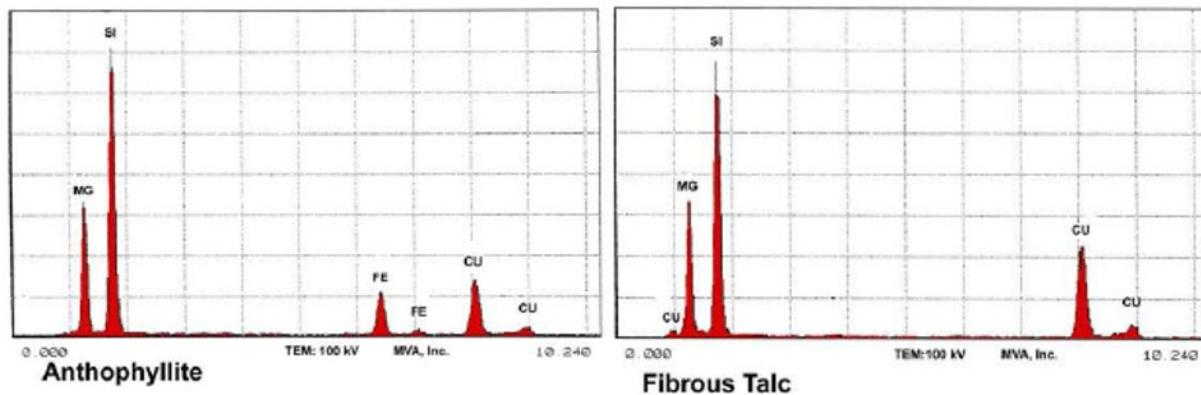
⁴ EDXA stands for “energy dispersive X-ray analysis,” ASTM D6281-09 ¶ 3.4, which is equivalent to the EDS (energy dispersive spectroscopy) analysis described above.

asbestos and non-asbestos analogues of the same amphibole mineral.” ASTM D6281 ¶ 1.1.2; see also ASTM D6281-09 ¶ 3.2.13 (defining “cleavage fragment” and stating “[s]ome cleavage fragments would be included in the fiber definition used in this method”). Thus, even for the particles MVA found that meet the method’s definition of a “fiber,” the method acknowledges that these fibers could still be cleavage fragments. *Id.* And MVA performed no additional analysis on those fibers observed during their AEM analysis to determine whether they grew in the asbestosiform habit and exhibit the generally accepted characteristics of asbestos; such as very high aspect ratios (20:1 to 100:1 or higher), parallel fibers occurring in bundles, fiber bundles with splayed ends, matted masses of individual fibers, and/or fibers showing curvature.

In a crushed and milled product like talcum powder, if either asbestosiform or non-asbestosiform amphibole is in fact present, as well as talc, they will produce particles with aspect ratios greater than 5:1. Hence, the morphological requirements of a fiber used in ASTM D6281 do not reliably differentiate asbestos fibers from non-asbestos fibers.

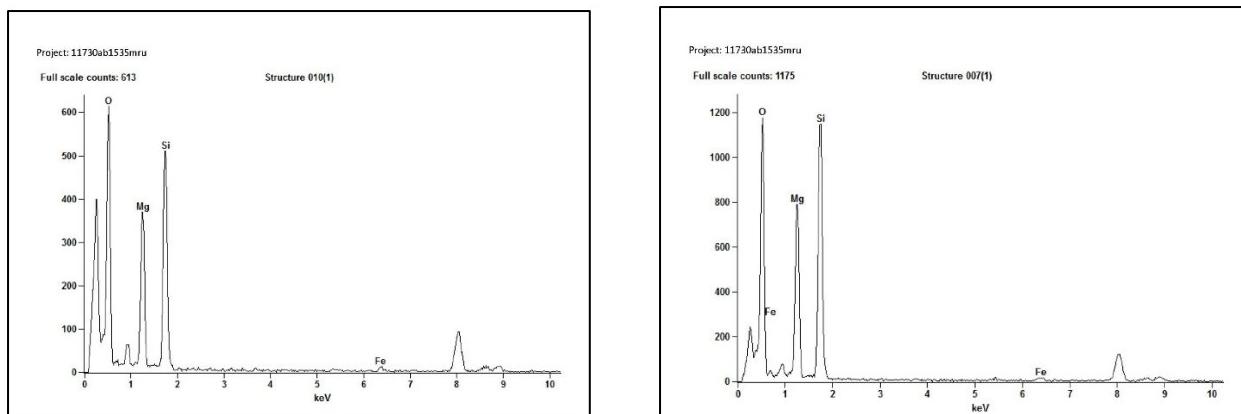
Chemical composition by energy dispersive x-ray analysis. In addition to a particle’s morphology, the ASTM D6281 method require the analyst to evaluate the fiber’s EDXA spectra to determine its chemical composition in order to properly identify it. ASTM D6281 ¶ 4.2. EDXA analysis can be performed quantitatively and non-quantitatively. Quantitative EDXA analysis is preferred, and in some contexts is required, for samples where known interferences have overlapping elemental composition. See NIOSH 7402 (stating that there are “several minerals,” including “talc fibers[] which are chemically similar to asbestos and can be considered interferences”); Int’l Agency for Research on Cancer, Vol. 93, at 286 (“Anthophyllite and sepiolite have chemical compositions that are very similar to talc and require quantitative chemical analysis to differentiate them, including the use of well characterized standards in the case of dispersive X-ray analysis used in conjunction with electron microscopy.”) I have reviewed MVA’s reports and have not seen any evidence that MVA performed a quantitative EDXA analysis of any of the particles they claimed were asbestos, nor did they do any comparative analysis to known interferences, such as talc where they report findings of anthophyllite.

MVA also made substantial errors in their analysis of the elemental chemistry of the fibers they claimed were asbestos. The most common asbestos mineral that MVA claimed to find was anthophyllite, and anthophyllite typically has iron in it. Dr. Compton teaches a course on AEM analysis at MVA, and those materials include images of EDXA spectra for both anthophyllite and talc:



MVA, "Fundamentals of Asbestos Analysis by TEM" at 145-47. As can be seen in the images above, talc has similar elemental chemistry to anthophyllite in all respects but one: talc generally lacks iron (note the "FE" peak near the center-right of the anthophyllite spectra, but the absence of the FE peak in the talc spectra).

The EDS spectra that MVA obtained from analyzing what it called "anthophyllite," however, often had no iron peak, and was therefore more consistent with a typical talc particle than a typical anthophyllite particle. Two examples of MVA's EDS spectra (EDS from 1173AB1535 Str_010 and Str_002) from particles MVA identified as anthophyllite are below, and neither have the iron peak characteristic of anthophyllite:



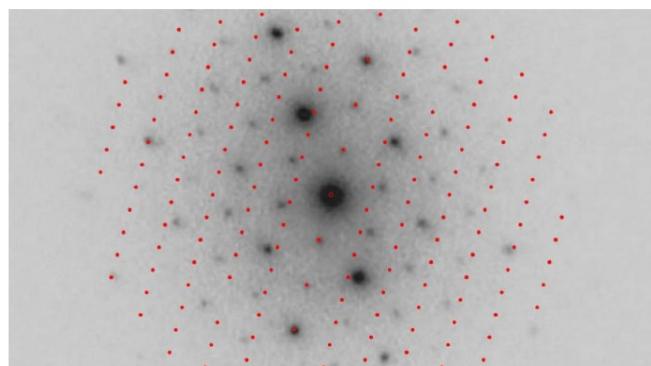
Theoretically, some talcs may have minor amounts of iron and some anthophyllites may have little to no iron, but as far as I am aware, the only documented source of iron-free anthophyllite in nature originates from an industrial grade talc deposit in upstate New York—an area that is not at issue in these cases as Johnson & Johnson did not use these mines as a source for its talcum powder production and it is my understanding that these mines were never a source for cosmetic or pharmaceutical talc.

Crystal structure by electron diffraction. In addition to analyzing a particle's morphology and chemical composition, ASTM D6281 require an analyst to evaluate the particle's SAED pattern to determine information about its crystal structure. ASTM D6281 ¶ 4.2. There are both non-quantitative and quantitative types of SAED analysis, and ASTM D6281 requires employing quantitative methods in order to "[c]onfirm amphibole" particles in samples whose contents are "unknown" (i.e., where asbestos is not known to be present), ASTM D6281-09 ¶ A4.4.3. The analyst does this by quantitatively comparing the zone axis SAED patterns from the particle to the published data for "all of the fibrous minerals likely to be encountered in TEM analysis of air samples." ASTM D6281 ¶ A4.3.2.1. The analyst must therefore compare a particle's SAED pattern not only to data for serpentine and amphibole minerals, but also to known non-asbestos interferences that may be in the sample. *Id.* at ¶ A4.3.2.3 ("Test even the structures of nonamphibole minerals in this preselected list against the zone-axis data obtained for the unknown fiber since nonamphibole minerals in some orientations may yield similar patterns consistent with amphibole structures.") For the case of a talc sample, the interferences include talc itself, as well as other non-asbestos minerals that can sporadically be found in talc, e.g. sepiolite.

Dr. Compton admitted that MVA failed to compare the measured SAED patterns against published data for talc and other common non-asbestos minerals found in talc. Apr. 13, 2017 Compton Dep. at 216:4-218:20. In other words, when analyzing talcum powder for the presence of amphibole, MVA failed to determine whether the data yielded a better fit for talc. If they had performed this analysis, MVA would have realized that the vast majority of the particles they called anthophyllite were, in fact, talc.

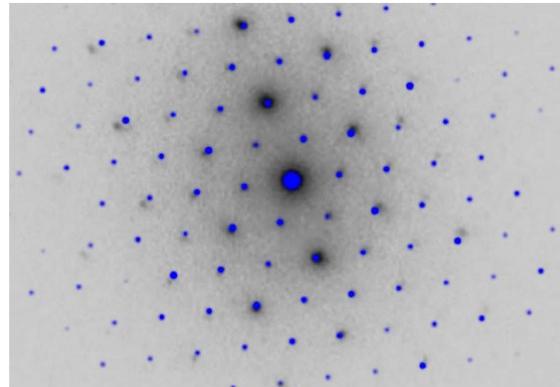
For example, the first image below shows the expected diffraction pattern for an anthophyllite particle at the [213] zone (in red, which is how MVA indexed the pattern) laid over the diffraction pattern that MVA recorded. It is readily apparent that the observed pattern and calculated pattern (red dots) do not match anthophyllite:

Observed SAED
overlain with [213]_{An} simulated



Conversely, the observed diffraction pattern matches the expected pattern (in blue) for talc at the [112] orientation.

Correct Index of observed pattern is
[112] Talc



(Sanchez List of Materials Reviewed and/or Relied Upon, Jan. 15, 2016 Examples of Incorrect Approach to Indexing Zone Axis SAED by MVA) at 5, 13.) The diffraction pattern, in other words, is a match for talc, not anthophyllite. But MVA did not check their SAED patterns against talc, and instead only checked them against anthophyllite and other amphibole minerals, which caused them to misidentify talc as anthophyllite. In fact, in one instance they incorrectly indexed a tremolite particle as anthophyllite).

In addition to failing to compare their SAED patterns to talc, MVA also failed to obtain two separate zone axis SAED patterns with consistent interaxial angle⁵ for each of the particles they analyzed, in violation of ASTM D6281. In an unknown sample, when the analyst finds fibers with non-tubular morphology,⁶ ASTM D6281 states that the analyst can “[c]onfirm amphibole only by” employing three types of analyses, which are called AZQ, AZZ, and AZZQ. ASTM D6281 ¶ A4.4.3. The acronyms AZQ, AZZ, and AZZQ are defined terms that represent quantitative SAED and/or EDXA analyses.⁷ For two of these analyses (AZQ and AZZQ), quantitative EDXA is required where the analyst measures and quantifies the chemical elements found in the particle. ASTM D6281

⁵ The “interaxial angle” is the angle between the two zone axes.

⁶ Chrysotile asbestos has a “tubular” morphology, and amphibole asbestos has a non-tubular morphology. Because MVA never reported detecting chrysotile asbestos, I focus here on the ASTM D6281’s methods for identifying fibers with non-tubular morphology.

⁷ AZQ means that the analyst has confirmed the amphibole mineral by obtaining a zone axis SAED pattern and quantitative EDXA consistent with amphibole. ASTM D6281 Table A4.2. AZZ means that the analyst has confirmed the amphibole mineral by obtaining two zone axis SAED patterns with a consistent interaxial angle that is consistent with amphibole. *Id.* And AZZQ means that the analyst has confirmed the amphibole mineral by obtaining two zone axis SAED patterns with a consistent interaxial angle and a quantitative EDXA, all of which are consistent with amphibole. *Id.*

Table A4.2. Because there is no evidence that MVA performed quantitative EDXA, MVA cannot satisfy the requirements of AZQ and AZZQ. ASTM D6281 Table A4.2. MVA was therefore required to confirm amphibole by AZZ analysis. ASTM D6281 Table A4.2.

MVA failed to perform an AZZ analysis that complied with ASTM D6281. An AZZ analysis requires obtaining two zone axis SAED patterns with interaxial angles that are *both* consistent with amphibole. ASTM D6281-09, Table A4.2, Fig. A4.4. If the first pattern is consistent with amphibole but the second pattern is not, or even if both patterns are consistent but the interaxial angle is not, then the analyst cannot report finding asbestos and must report “NAM,” or “non-asbestos mineral.” *Id.*

Dr. Compton admitted in deposition that he failed to follow all of these requirements. Apr. 13, 2017 Compton Dep. at 216:4-218:20. Based on the testing reports I have reviewed, for the majority of the particles MVA analyzed, MVA performed only one zone-axis analysis on those particles. One zone axis measurement is not sufficient to meet an AZZ analysis, and none of those particles can be identified as asbestos under ASTM D6281. ASTM D6281 ¶ A4.4.3; Table A4.2.

MAS

I have reviewed reports by Dr. Longo of MAS as well as various deposition and trial testimony as it relates to his testing of alleged bottles of Johnson & Johnson talcum products. The specific reports I have reviewed are dated August 2, 2017, August 21, 2017, September 2017, October 2017, February 16, 2018, March 2018, March 11, 2018, October 2018 (two reports), November 5, 2018, November 14, 2018, January 15, 2019, February 2019, February 9, 2021, and April 13, 2021. Criticisms of the MAS testing conducted on the MDL samples are expounded in a report dated February 12, 2019 and summarized herein. Additional criticisms of MAS testing are found in a report dated May 10, 2023.

Dr. Longo and MAS used the same counting rules as employed by MVA (discussed at length above) that are incapable of differentiating asbestos from non-asbestos minerals. The finding of small amounts of amphiboles in sporadic samples potentially originating from these deposits is consistent with the geology and testing records of both the Vermont and Italian source mines, and do not constitute a finding of asbestos. MAS further failed to use any objective measurements of observed electron diffraction patterns and without this data they cannot show that the observed particles are in fact amphibole and even if these were proven to be amphibole by supplemental work the diffraction data alone is insufficient to determine if any particle is asbestosiform.

Dr. Longo does not properly follow the ISO 22262-1 Method for PLM analysis. 1. Dr. Longo's report claims he analyzed 42 talc samples using the ISO 22262-1 method for PLM analysis. (See Nov. 14, 2018 MAS Report, at p. 16.) Dr. Longo fails to measure correctly the refractive index of the alleged minerals observed, this results in his incorrect identification of anthophyllite asbestos

by PLM. In Figure 10.1 are two images from Dr. Longo reports showing the refractive index measurement in both the parallel and perpendicular directions -arrows added- (See Nov. 14, 2018 MAS Report, at p. 581-582.) Note, that the color observed (which is a function of the refractive index) does not change as a function of orientation. Shown directly below are the correct colors that would be displayed if these particles were in fact anthophyllite. The lower pair of images are taken from ISO 22262-1 (at p. 51) and illustrates both the refractive index and morphology of anthophyllite asbestos in same two particle orientations as the images supplied by Dr. Longo.

Dr. Longo anthophyllite vs. ISO 22262-1 anthophyllite asbestos

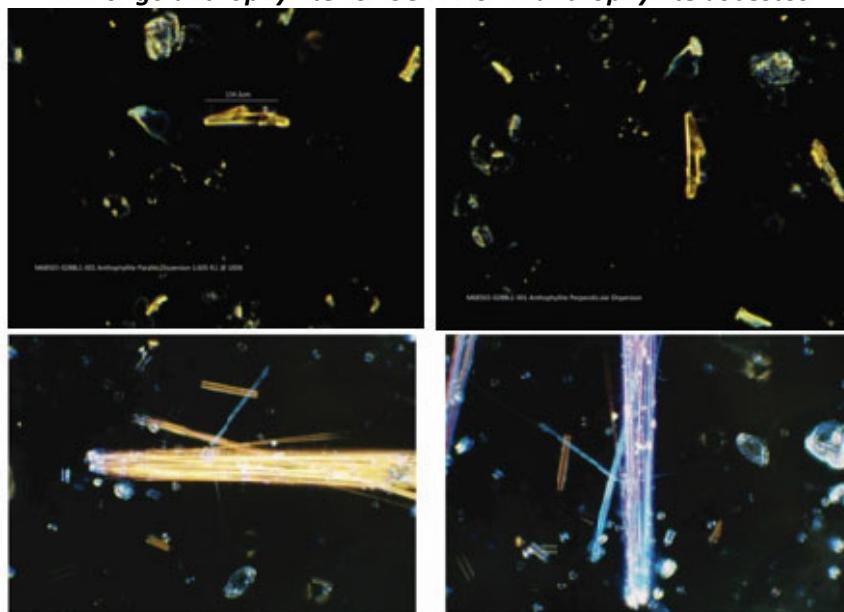


Figure D.47 — HSE anthophyllite in 1,605 RI liquid viewed in dispersion staining — Fibre lengths parallel to polarizer vibration direction

Figure D.48 — HSE anthophyllite in 1,605 RI liquid viewed in dispersion staining — Fibre lengths normal to polarizer vibration direction

ISO 22262-1**7.2.3.7 Identification of asbestos****7.2.3.7.1 Morphology**

A detailed description for the morphology that is characteristic of asbestos is as follows. This morphology is characteristic of the larger fibres seen in stereomicroscope examinations and of fibres selected from laboratory samples for PLM identification of fibre type.

In the light microscope, the asbestiform habit is generally recognized by the following characteristics:

- a) the presence of fibre aspect ratios in the range of 20:1 or higher for fibres longer than 5 µm;
- b) the capability of longitudinal splitting into very thin fibrils, generally less than 0,5 µm in width;
- c) in addition, observation of any of the following characteristics for the fibre type under consideration provides additional confirmation that the fibres are asbestiform:
 - 1) parallel fibres occurring in bundles,
 - 2) fibre bundles displaying splayed ends,
 - 3) fibres in the form of thin needles,
 - 4) matted masses of individual fibres,
 - 5) fibres showing curvature.

In practice, if chrysotile, crocidolite or amosite is identified in a commercial product, the assumption can safely be made that the fibres are asbestiform and that these fibres conform to the description above. This assumption can be made because these three types of asbestos were mined and processed to yield fibres with specific properties for intentional incorporation into products. Some anthophyllite asbestos was used in a few commercial products, but very little was mined and used commercially. Tremolite asbestos has been found in some surfacing and fireproofing applications in Japan. However, other than these occurrences, the amphiboles tremolite, actinolite, and richterite/winchite were not generally used in commerce, and their presence in a product is more likely a consequence of naturally occurring contamination of one or more of the major constituents. Accordingly, no assumption can be made as to whether the amphibole is asbestiform or non-asbestiform. Anthophyllite can occur as contamination of other mineral products, and in such situations no assumption can be made as to whether it is asbestiform or non-asbestiform. In some samples, these amphiboles may exhibit a mixture of morphological types, and quantitative determination of the regulatory status of such samples may require a detailed study of the fibre size distribution that is beyond the scope of this part of ISO 22262.

In general, for this part of ISO 22262, the presence of either the asbestiform or the non-asbestiform analogues of tremolite, actinolite, anthophyllite or richterite/winchite can usually be specified. If the majority of the amphibole fibres longer than 5 µm have aspect ratios equal to or lower than 5:1, and if the fibres do not exhibit any of the characteristics in c), it can be concluded that the amphibole is probably non-asbestiform, with the degree of certainty increasing with decreasing maximum aspect ratio. If any amphibole fibres longer than 5 µm with aspect ratios in the range of 20:1 or higher are observed, then it can be concluded that amphibole asbestos is probably present, with the degree of certainty increasing with increasing aspect ratio.

(ISO 22262-1 Method, at pp. 22-23.)

In his application of the method, however, Dr. Longo disregards the method's definition of asbestiform. (See Nov. 14, 2018 MAS Report, at pp. 19-20.)

ISO 22262-1

2.8

asbestiform

specific type of mineral fibrosity in which the fibres and fibrils possess high tensile strength and flexibility

[ISO 13794:1999,^[4] 2.6]

(*Id.* at p. 2.)

Rather, Dr. Longo assumes any amphibole that is elongated (>3:1 aspect ratio) are asbestiform. (*Ibid.*) This is especially problematic as the method specifically states no assumptions can be made as to whether observed anthophyllite, tremolite, and actinolite are asbestiform. Furthermore, ISO 10312 (an air method), which uses a 3:1 aspect ratio counting criteria specifically states, “The method cannot discriminate between individual fibres of the asbestos and non-asbestos analogues of the same amphibole mineral.” (ISO 10312 “Ambient air – Determination of asbestos fibres – Direct-transfer transmission electron microscopy method” p. 1 sec. 1.1).

Dr. Longo’s report also fails to identify how he identified the particular structures as bundles other than describing the structures as “parallel fibers in an asbestos structure that are closer than one fiber diameter to each other.” (Nov. 14, 2018 MAS Report, at p. 19.) This is particularly concerning as Dr. Longo concedes an outside laboratory was unable to identify any asbestiform particles in the 38 samples of the Defendants’ talc it tested from the same time period using the same methodology followed properly. (*Id.* At 13.)

In sum, Dr. Longo materially deviates from the ISO 22262-1 method in a manner that is novel and not generally accepted by the scientific community.

Furthermore, Dr. Longo’s comparison of his observed data to the data found in the 1977 Bureau of Mines report to conclude a finding of asbestos is a false comparison. The MAS data consists of only amphiboles that have aspect ratio’s greater than 5:1 and longer than 0.5um in length (MAS’s chosen counting criteria). When one compares the Bureau of Mines report the comparisons of the asbestos vs. non-asbestiform amphiboles were conducted on measurements of all particles in all size and shape ranges. Thus in order to use the Bureau of Mines data for comparative purposes MAS must collect all the dimensional data of the particles within the product samples and then compare the aspect ratio distributions. Furthermore, MAS must show that the TEM preparation process does not bias the particle distributions through loss of the larger particulate. When I used a one-to-one comparison of the observed MAS particle population the distribution is consistent with non-asbestiform amphibole. By not comparing the same type of dimensional data MAS compared two disparate data sets and arrived at a false positive result for asbestos.

The claim of Dr. Longo that the mineral chesterite is a polymorph of anthophyllite is false. The term polymorphism refers to minerals that have the same chemical composition but different crystal structures. This is not the case between chesterite and anthophyllite, they both have a unique chemical composition (end member formulas $Mg_{17}Si_{20}O_{54}(OH)_6$ and $Mg_7Si_8O_{22}(OH)_2$) and unique orthorhombic crystal structures ($a= 18.64$, $b= 45.31$, $c=5.29$ and $a=18.54$ $b=18.02$, $c=5.28$ respectively). The methods used for both compositional and diffraction analysis conducted by MAS is incapable of distinguishing these two minerals.

The comparison of a modern day talcum powder's particle size distribution does nothing to verify whether a talcum powder obtained from a third party seller is the same material that would have been placed in the bottle during manufacturing. Talc products are milled to certain size parameters for a variety of applications. The end user of the talc defines the particle size needed for the intended application and these sizes are not unique to any given product or manufacturer. For example, an industrial grade talc that is milled to 200 mesh would have a comparable particle size distribution to a cosmetic grade talc milled to a 200 mesh. The particle size comparison between the two simply confirms that the talcum powder tested has been milled to the same specification but it does not establish provenance of a material or the end use application of the powder. The particle size distribution would only be a unique marker if Johnson & Johnson used a uniquely milled particle size, this is not the case with current production nor have I seen evidence that this was true in the past.

Furthermore, I have tested thirty-one (31) of the alleged Johnson & Johnson powders analyzed by MAS and relied upon by Dr. Longo and found that only one of the samples contained tremolite asbestos which was observed despite the presence of non-asbestiform amphibole in sample 3149796, a sample drawn from a pre-1953 cardboard container. This container is from the early 1940's and is unique when compared to the remainder of the samples analyzed. It is in no way representative of the whole sample set of containers. The asbestiform component is clearly observable by PLM and TEM without any concentration techniques being employed. Any other amphibole observed in the other samples were non-asbestiform and consistent with amphiboles of the monoclinic crystal system, i.e. cannot be anthophyllite.

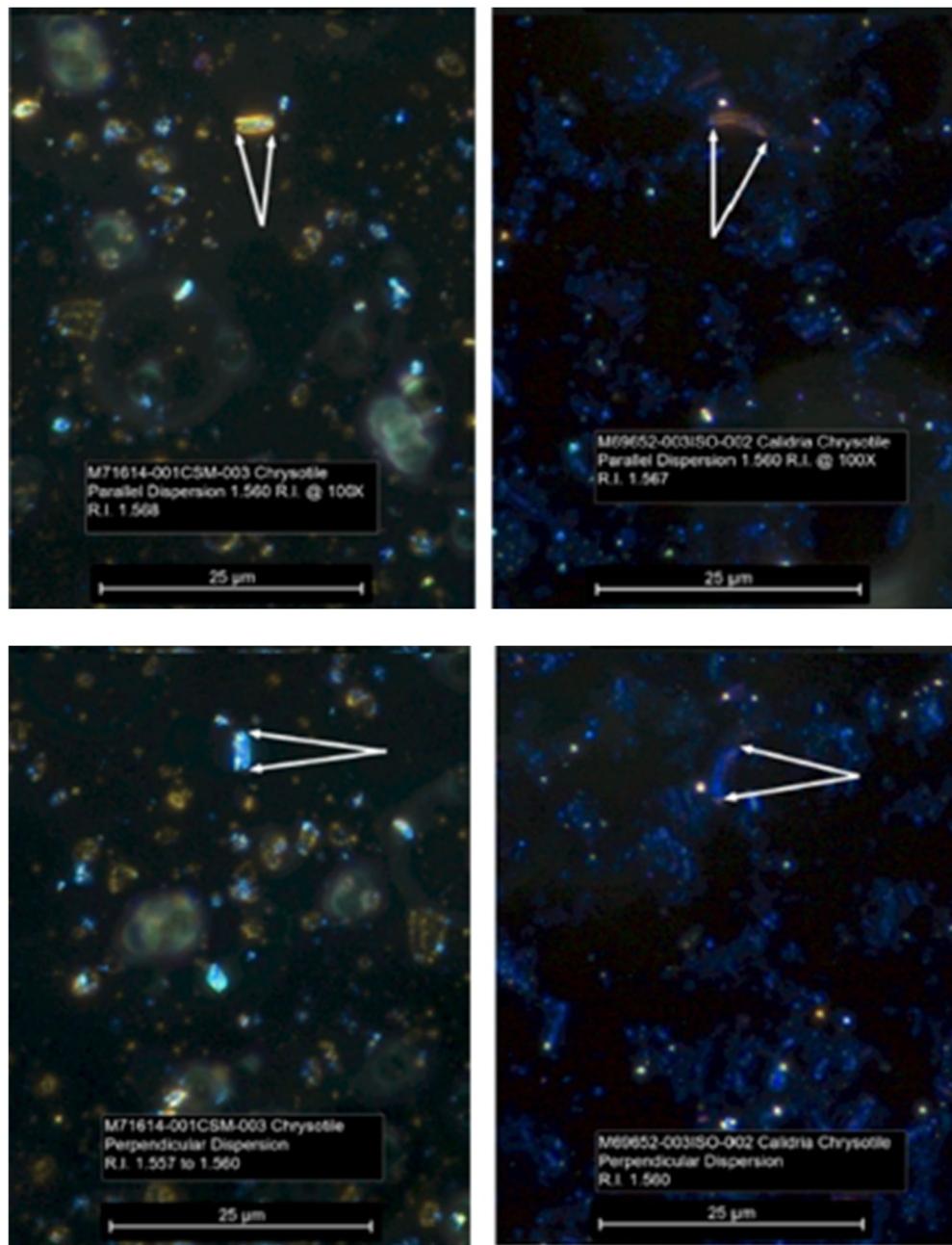
I have also reviewed the two MAS Baby Study Simulations dated January 2019 and June 28, 2019 rev. 1 as well as the MAS Supplemental Baby Study dated May 2020. There are numerous incongruities in the data presented in these reports which need to be addressed. The two samples selected for the studies are the two highest amphibole containing talc samples drawn from Johnson & Johnson containers. The sample used in the January 2019 report (M66173-003) contains primarily non-asbestos amphibole with a subordinate amphibole asbestos component. The sample used in the Baby II Study contained no detectable amphibole asbestos component. Thus, the assumption that all the amphibole observed in a simulation must be asbestos is erroneous and this assumption will exaggerate amphibole asbestos f/cc values in both studies. The concentration of amphibole in these two samples are orders of magnitude greater than other talc samples (where amphibole is observed) drawn from Johnson & Johnson product containers.

Furthermore, for the January 2019 report, 74 out of 74 counted amphibole particles all were identified as tremolite by MAS and no chrysotile was observed in any of the air samples generated in this study. However, in the fabric sample WC-1-C, MAS reported chrysotile ($n = 5$) and no tremolite. The source of chrysotile needs to be determined as there is no evidence to support a conclusion that it came from the talc. When comparing the NIOSH 7400 (PCM) and NIOSH 7402 (TEM) data for the six personal samples from the January 2019 report, the percentage of fibers that were identified as asbestos by TEM ranged from 0 (P-1-A) and 100 (P-1-D). The minimum and maximum asbestos fiber to total fiber ratio presented in this small sample set, from the same simulation and the same material source, is highly suggestive of either a sampling or analysis error. Talc fiber is always a component of any talc-based sample (not to be confused with either fibrous or asbestiform talc). The near lack of recorded talc fiber in the TEM analysis for both studies further indicates that the total fiber count of the TEM data is not reliable, thus the “asbestos” percentages reported are not valid.

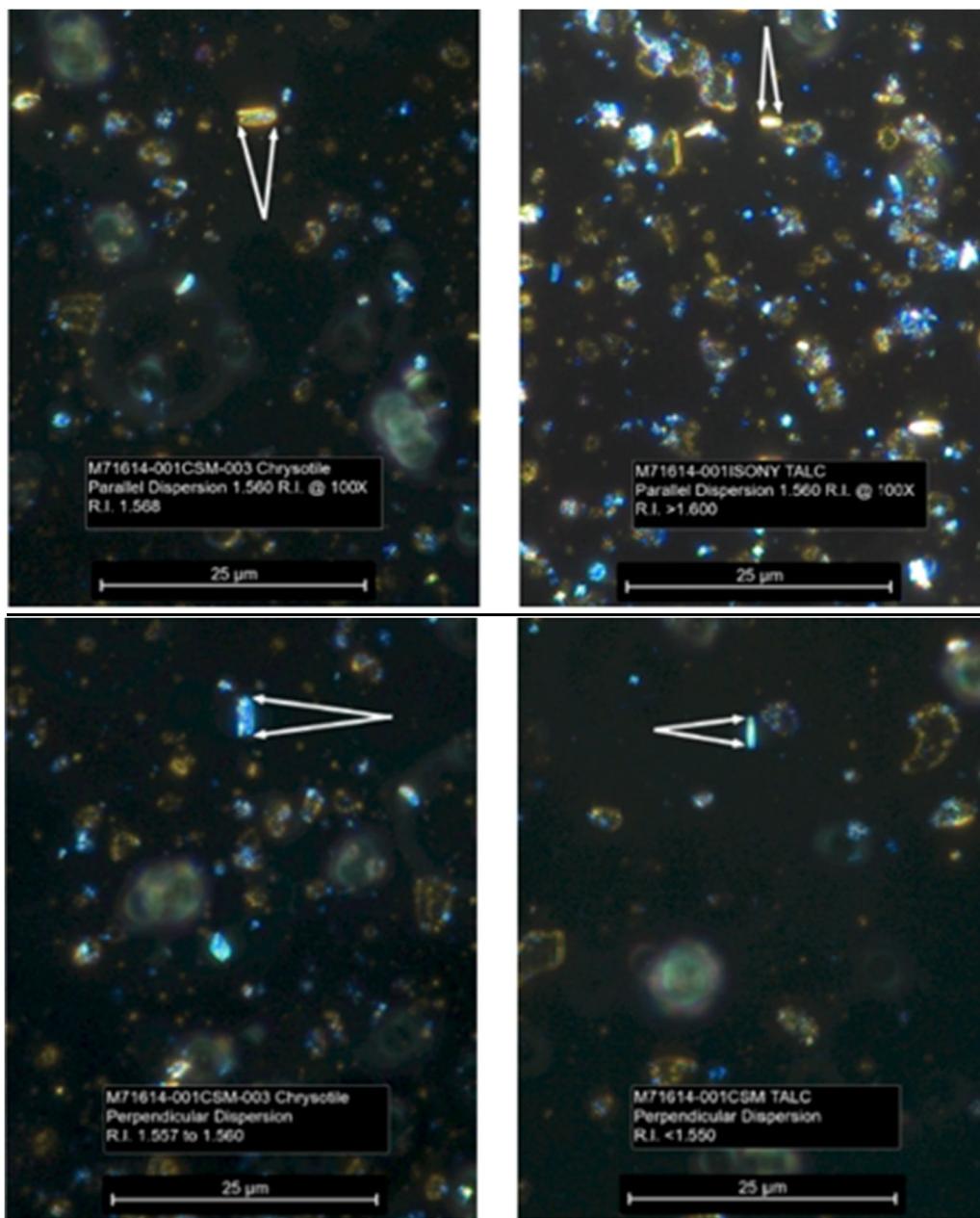
Dr. Longo has also issued a number of reports (Zimmerman Feb 24, 2020; Citizen Mar 6, 2020; Doyle Mar 20, 2020; Titley Mar 18, 2020 and May 14, 2020; and Colley Apr 6, 2020) wherein he purports to identify chrysotile using an iodine staining procedure. Discussion of this procedure and the effects thereof are discussed in my reports dated March 9, 2020 (Zimmerman) and April 29, 2020 (Titley).

I have reviewed reports dated September 16, 2020, and September 17, 2020 (supplemental dated September 29, 2020) which comprised testing of GuangXi Chinese source talc and “off the shelf” testing of Johnson & Johnson baby powder. In these reports, Dr. Longo continues to misidentify talc as chrysotile. This error is the same error as discussed in my rebuttal reports of March 9, 2020 and April 29, 2020. Dr. Longo has demonstrated a lack of understanding of optical crystallography and how it is used in mineral characterization and identification. Furthermore, the optical measurements given by Dr. Longo, even though erroneous, are still inconsistent with chrysotile optical data in the published literature and generally accepted PLM based general methods. For example, Longo’s chosen method for this analysis is ISO 22262, however he completely disregards the published known chrysotile ranges for γ and α , see Figure C.1. Ironically the matching (λ_o) color that MAS interprets as γ for chrysotile is the same color (same refractive index) as the talc plates in the same photograph.

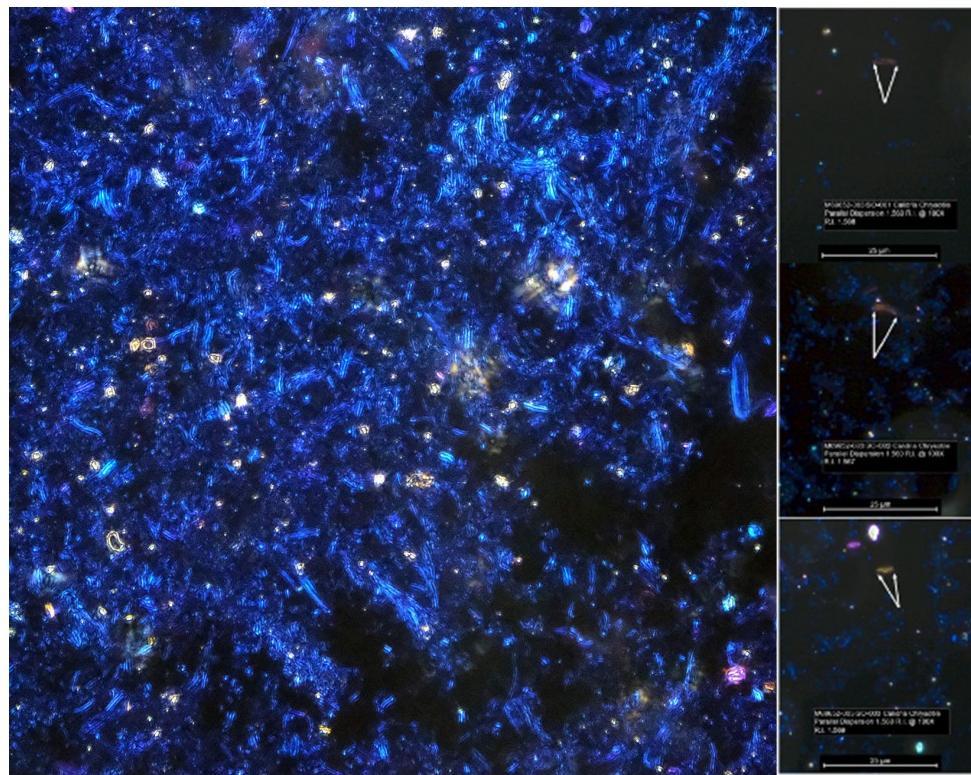
I have reviewed a single bottle test report of Dr. Longo dated February 28, 2023. In this report Dr. Longo again changes his testing approach by PLM as it relates to the alleged findings of chrysotile. The primary change is using a 1.560 instead of the previously used 1.550 refractive index liquid. This further demonstrates that, as discussed above, talc is being misidentified as chrysotile. I discuss these findings in a report dated May 10, 2023, and its revision dated June 20, 2023. Below are comparisons of what Dr. Longo is alleging is chrysotile in the 1.560 liquid to the Calidria chrysotile.



Note that the colors are not the same, meaning that they cannot be the same mineral. Further, note below this same particle compared to what Dr. Longo reports as talc (this I agree with). The alleged chrysotile exhibits the same colors as the talc. Thus, the alleged chrysotile is talc.



Dr. Longo also misrepresents the refractive index of the Calidria chrysotile in his reports and prior testimony. The comparisons made above are to a mineral phase within the Calidria material, but it is not representative of that chrysotile. Below on the left is an image of a representative field of view of the Calidria chrysotile material in a 1.560 liquid. The three images on the right were produced by Dr. Longo as representative of the Calidria material. Supporting this are refractive index measurements provided in the literature for Calidria sourced chrysotile; both McCrone 1974 and Campbell et al. 1980 provide refractive indices measurements for both γ' and α' in either λ_o or in n_D , respectively. McCrone 1974 reports 590nm and 630nm in 1.550 reference liquid and Campbell reports 1.562 and 1.557 respectively.



I have reviewed the deposition of Dr. Longo in the Cardillo case given on September 1, 2023 wherein Exhibit 13 is an affidavit dated August 28, 2023. Exhibit 13 included a report of Dr. Shu-Chun Su regarding the misinterpretation of Dr. Su's work cited by Dr. Longo to support Dr. Longo's erroneous chrysotile findings. The testing reviewed by Dr. Su is directly relevant to this case as Dr. Longo uses the same systematically flawed approach and rational in his testing on Johnson & Johnson talc products. In his review Dr. Su states:⁸

"MAS misinterpreted my conversion tables for chrysotile in Cargille 1.550 (Series E) R.I. liquid. Those tables do not define the ranges of chrysotile's refractive indices. Instead, they are used to convert RI matches between the liquid and solid at matching wavelengths other than 589nm, back to the reported values that are given at 589 nm."

Dr. Longo misinterprets Dr. Su's work to justify his chrysotile findings by falsely comparing his observed refractive indices (albeit incorrectly measured) with the tables of Dr. Su to claim his observations are chrysotile and that his approach is consistent with the scientific literature. Dr. Longo is using both a novel and unsound testing protocol.

⁸ Exhibit 13 – Deposition of Dr. William Longo in Cardillo vs. American International Industries et al. New York September 1, 2023.

J3 Resources

As noted above, Mr. Poye analyzed 16 samples of Shower to Shower obtained through the MDL process. A more thorough review of J3 Resources testing of these samples was produced in a separate report dated February 12, 2019. I will summarize that report here.

As noted above, Mr. Poye of J3 Resources analyzed 16 samples of Shower to Shower obtained through the MDL process. A more thorough review of J3 Resources testing of these samples was produced in a separate report dated February 12, 2019. I will summarize that report here.

The analysis of Mr. Poye failed to screen adequately by PLM for amphibole mineral phases and did not find any asbestos because it is simply not present in those bottles. Regarding his TEM testing, he failed to conduct quantitative zone axis indexing correctly and arrived at the false positive result of anthophyllite asbestos in 11 of the 16 samples. This false positive result is due to his failure to index his zone axis diffraction patterns, when evaluating his zone axis diffraction patterns and indexing them, one finds that they are consistent with particles derived from talc to amphibole reactions and many of the particles are in fact transitional particles, or intergrowths of various biopyribole phases, (e.g. talc, cummingtonite, and clinojimthompsonite). Thus, Mr. Poye's own testing and back-up data has in fact shown that there is no asbestos present in the 16 samples tested when mineral identification is conducted correctly.

R. Mark Bailey, P.G.

I have reviewed reports of Mr. R. Mark Bailey regarding Italian and Vermont sourced talcs used by Johnson & Johnson dated May 9, 2018, March 1, 2020 and November 16, 2020. I have also reviewed Mr. Bailey's deposition in the Biermann matter and other cases along with various affidavits and exhibits to said depositions. I have provided sworn testimony regarding many of Mr. Bailey's geological opinions where he is in error in previous cases as it regards his erroneous conclusions of cosmetic grade Italian talc mined in Val Germanasca, Italy and Vermont.

With regard to Italy, while I agree with Mr. Bailey that primarily tremolite and possibly actinolite may be found in some of both the country rock and in the inclusions within the talc ore, the crystallization habit of these amphiboles are non-asbestiform i.e. not asbestos, thus the amphiboles present are not amphibole asbestos. To assume that a reference to the detection of tremolite is proof of tremolite asbestos is not based in sound science and cannot be made unless methodologies are used that make such a distinction. Mr. Bailey has conducted no such tests and instead relies on local mineralization in other rock units in the Alps or in the United States.

The paper by Van Gosen et al. 2007 in regard to the presence of both asbestiform and non-asbestiform amphiboles occurring with talc comes from direct observations of specific talc mines located in southern Death Valley, California. The formation of the talc in southern Death Valley is by contact metamorphism with the emplacement of an intrusive mafic sill in contact with the Crystal Spring formation. This talc formation process is not the same as the talc formation

conditions at Val Germanasca (or Vermont) and it is inaccurate to equate the two. The “mixing” of wall rock and the inclusions with the talc is minimal and in order for asbestos to be introduced by these materials asbestos would have to be present in these rocks. No asbestos is present in these rocks, thus no asbestos can contaminate the talc ore from these sources as a result of the mining process.

The efficiency of the talc beneficiation process is well documented in the testing records of Val Germanasca that I reviewed and in my personal observations during my site visit in 2015. Furthermore, where one compares the finished milled talc to hand samples of the talc ore – with no contribution of inclusions or wall rock- there is no significant difference in the mineralogy of the samples. This shows that the contribution of the inclusions in the talc and/or inclusions of wall rock is minute and is insignificant to the bulk mineralogy of the final ground talc product. Even if a significant portion of the wall rock and inclusions were included in the final talc product the wall rock and inclusions do not contain asbestos.

Mr. Bailey states: “The geologic processes and conditions which create talc ore deposits (burial at depth, elevated temperatures, the presence of fluids, etc.) are in almost all cases the same as those which cause amphibole asbestos minerals to form...” This statement is without basis and is too general. It is true that these same mechanisms, e.g. temperature, fluids, burial, etc. enable minerals to form, but to state categorically that since both talc and asbestos are minerals these natural processes must always form talc and asbestos together is in error. Furthermore, in various talc deposits studied by NIOSH in 1977, and more recently by the USGS (Van Gosen et al. 2007) in the United States, it was found that a minority of talcs tested contained amphibole, and even fewer contained asbestos. Furthermore, Mr. Bailey continually equates amphibole with findings of amphibole asbestos. While it is true all asbestos is fibrous not all fibers are asbestos. In other words, Mr. Bailey is conflating the identification of asbestos with the counting of asbestos.

In regard to Vermont Van Gosen et al. 2007, Mr. Bailey grossly misconstrues the findings. The only talc sources studied in that paper wherein Van Gosen reports asbestos are not at issue to Johnson & Johnson, and to my knowledge were never used for cosmetic purposes. For example, the asbestos in talc reported from North Carolina are associated with the Day Book Dunite and any talc associated with that deposit was never of cosmetic grade or quality. Ironically, Mr. Bailey ignores that Van Gosen looked at the Vermont type deposits and does not report any asbestos present (discussed above).

To support his conclusions, Mr. Bailey cites to Chidester 1951. Chidester worked for the USGS and studied, among other interests, the talc deposits in Vermont. In fact, Chidester had personally visited some of the talc mines active during the 1940’s through 1960’s. Mr. Bailey summarizes many of the observations reported by Chidester, however none of the citations report amphibole asbestos nor deal with the mines at issue for Johnson & Johnson. For example, “actinolite in rosettes from 1 to 3 inches across are found” is not the asbestos habit.

Chidester, in his work for the USGS, was familiar with asbestos and in his work cites to occurrences of asbestos in relatively unspuritized peridotites and dunites in Vermont (Chidester and Shride 1962). He does not report asbestos associated with the talc deposits, only amphibole in spatially constrained areas primarily of the black wall zone.

Sanford 1982 is also cited by Mr. Bailey and provides a detailed mineralogical examination of the reaction that forms the talc over a range of pressure and temperature conditions as one proceeds from the south to the north of Vermont. Mr. Bailey focuses on what is identified at the Grafton locality. Sanford describes this locality as a series of abandoned soapstone quarries, not talc mines. Regardless, the scale of the reaction is important as the cross section of the entire talc reaction zone is approximately 50 cm (or 1.6 feet). Contrast this to the isopach map of the Hammondsville talc ore (Figure 10 November 16, 2020 report) where the talc ore thickness being mined varies from 25 to 100 feet thick. Furthermore, the ore bodies at Hammondsville and Argonaut are in talc carbonate zones that are absent at Grafton. Thus, any direct inferences between talc ores at Hammondsville or Argonaut, or other past producing talc mine for Johnson & Johnson are not supported by the data. More recently, the USGS (Robinson et al. 2006) outlines the reaction zones within the Frostbite mine and they do not report any amphiboles nor similar mineral assemblages and modes as that referenced by Sandford at Grafton, or any of the other areas Sandford studied. Sandford also does not report asbestos in any of the localities he studied.

Mr. Bailey cites the work performed by Dr. F.D Pooley on behalf of Johnson & Johnson and while Dr. Pooley does not report asbestos, Mr. Bailey somehow finds it in the very same photographs Dr. Pooley presented in his report where he clearly states his findings as not asbestos in nature. This procedure of taking a poorly rendered copy of a copy of a photograph from the 1970s and somehow being able to interpret them in a manner such to contradict the findings of the original researcher who actually examined the samples by comparing it to other images from localities is not objective and not scientifically valid.

Furthermore, for Mr. Bailey to criticize techniques developed and being used in the early 1970's and somehow compare it to what we do today is not an objective means of analysis. For example, on page 32 of the November 16, 2020 report, Mr. Bailey criticizes the lack of compositional information by TEM. However, TEM did not have compositional analysis available at the time this study was conducted; the incorporation of EDS technology on TEM analysis was developed later. Another such example is the criticism of XRD results not distinguishing tremolite from actinolite. This differentiation could be done reliably using standard XRD techniques of that time or even today. Dr. Pooley did find monoclinic amphibole in discrete locations in the mine, and the nature of that amphibole was not asbestiform.

Lastly, Mr. Bailey has not tested any samples of talc from Johnson & Johnson (whether from Italy or Vermont) that I am aware of. There is some reference to potentially three samples from another plaintiff attorney, but he will not speak to results, citing privilege. Unlike Mr. Bailey, I

have examined numerous talc samples of Johnson & Johnson using modern and generally recognized testing procedures of the talc that would have been derived from Hammondsville and Argonaut. In no sample to date have I found amphibole asbestos. These testing results are discussed further in this report and in my reliance materials for the testing of the specific samples.

Conclusion

In my expert opinion, Johnson & Johnson talcum powder and talc from the source mines was and is free of asbestos. This opinion is offered to a reasonable degree of scientific certainty. This opinion is based on my expertise, education, training, and experience in analyzing materials, including talc, for possible asbestos content. This opinion is supported by my own site visits to both Val Germanasca Italy and Guangxi China, testing that I have conducted of the relevant talcs and upon my review, analysis, and interpretation of decades of study conducted by scientists in academia, federal government, and industry. This opinion is also supported by my review, analysis, and interpretation of the available analytical testing data on Johnson & Johnson talcum powder.

I reserve the right to amend this report if additional relevant information is made available to me.

Sincerely,



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Reference cited

- Blount, A.M. (1991) Amphibole Content of Cosmetic and Pharmaceutical Talcs. Environmental Health perspectives Vol. 94, pp. 225-230.
- Boundy, M.G., Gold, K., KP Martin, K.P., Jr., Burgess, W.A., and JM Dement, J.M. (1979) Occupational exposures to non-asbestiform talc in Vermont. In: Dusts and Diseases. R. Lemen & JM Dement (eds). Pathotox Publishers, Inc., Park Forest, IL. pp. 365-378.
- Buzon, M.E. (2016) Talc Characterization: A Provenance Study. PhD Dissertation, The University of Idaho, College of Graduate Studies.
- Dyar, M.D. and Gunter, M.E. (2008) Mineralogy and Optical Mineralogy. Mineralogical Society of America, Chantilly, Virginia, 708 pp.
- Cadoppi, P., Camanni, G., Perrone, G., Damiano, A., and Monticelli, F. (2012) Geometry reconstruction of the Fontane talc mineralization (Germanasca Valley, Italian Western

- Alps): integration of geological-structural analysis and geomatics methods. *Rend. Online Soc. Geol. It.*, 22, 33-35.
- Campbell, W.J., Blake, R.L., Brown, L.L., Cather, E.E., and Sjoberg, J.J. (1977) Selected Silicate Minerals and Their Asbestiform Varieties. Mineral Definitions and Identification-Characterization. United States Department of the Interior. Bureau of Mines Information Circular 8751.
- Ciocan, C., E. Pira, M. Coggiola, N. Franco, A. Godono, C. La Vecchia, E. Negri, P. Boffetta. (2022) Mortality in the cohort of talc miners and millers from Val Chisone, Northern Italy: 74 years of follow-up. *Environmental Research*. 203 111865.
- Coggiola, M., Bosio, D., Pira, E., Piolatto, P.G., La Vecchi, C., Negri, E., Michelazzi, M., and Bacaloni, A. (2003) An update of a mortality study of talc miners and millers in Italy. *American Journal of Industrial Medicine*, 44, 63-69.
- Doolan, B.J. (1996) The geology of Vermont. *Rocks and Minerals*, Vol. 71, pp. 218-225.
- Gattinoni, P., Scesi, L., Abdin, E.C., and Cremonesi, D. (2013) Hydrogeological risk and Mining Tunnels: the Fontane-Rodoretto Mine Turin (Italy). *World Academy of Science, Engineering and Technology*, 73, 224-228.
- Gunter, M.E. (2010) Defining asbestos: Differences between the built and natural environments. *CHIMIA*, 64, 747-752.
- Gunter, M.E., Belluso, E., and Mottana, A. (2007a) Amphiboles: Environmental and health concerns. In *Amphiboles: Crystal Chemistry, Occurrences, and Health Concerns, Reviews in Mineralogy and Geochemistry*, 67, 453-516.
- Gunter, M.E., Sanchez, M.S., and Williams, T.J. (2007b) Characterization of chrysotile samples for the presence of amphiboles from the Carey Canadian deposit, southeastern Quebec, Canada. *Canadian Mineralogist*, 45, 263-280.
- IARC (2010) IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans: Volume 93, Carbon, Titanium, and Talc. Lyon, France.
- Krause, J.B., and Ashton, W.H. (1977a) Misidentification of Asbestos in Talc. *National Bureau of Standards Special Publication* 506.
- Krause, J.B. (1977b) Letter to the editor RE: Consumer talcums and powders: Mineral and chemical characterization. *Journal of Toxicology and Environmental Health*. Vol. 2 pp. 1223-1226.
- Li, X.H. (1999) U-Ph zircon ages of granites from the southern margin of the Yangtze Block: timing of Neoproterozoic Jinning: Orogeny in SE China and implications for Rodinia Assembly. *Precambrian Research*, 97, 43-57.
- Lollino, G., Giardino, M., Allasia, P., Baldo, M., and Giordan (2004) Instrumented experimental sites for the control of landslide hazards in mountain environments: The Germanasca and Susa Valleys (Northwestern Italy). *32nd International Geological Congress, Field Trip Guide – P41*.
- McCarthy, E.F., Genco, N.A., and Reade, E.H., Jr. (2006) Talc. In *Industrial Minerals and Rocks*, eds., Kogel, J.E., Trivedi, N.C., Barker, J.M., and Krukowski, S.T. Society for Mining, Metallurgy, and Exploration, Inc., Littleton, Colorado, 971-986.

- McCrone, W.C. (1980) The Asbestos Particle Atlas. Ann Arbor Science Publishing Inc. The Butterworth Group, Michigan.
- National Institute Occupational Safety and Health (NIOSH or McCrone) (1977) Analysis of Talc by X-ray Diffraction and Polarized Light Microscopy. Walter C. McCrone Associates, Inc. Chicago IL.
- Peila, D., Oggeri, C., Oreste, P., Polizza, S., and Monticelli, F. (2008) Rodoretto talc mine (To, Italy): studies for the optimization of the cemented backfilling. RMZ – Materials and Geoenvironment, 3, 283-306.
- Peretti, L. (1978) Geologia e genesi dei giacimenti di talco nel Pinerolese [translated title = Geology and genesis of the talc deposits in the Pinerolese]. Boll. Ass. Min. Subalpina, 3, 283-306.
- Pira, E., Coggiola, M., Ciocan, C., Romano, C., La Vecchia, C., Pelucchi, C., Boffetta, P. (2017) Mortality of Talc Miners and Millers from Val Chisone, Northern Italy. JOEM, Vol. 59, Number 7, pp. 659-664.
- Pooley, F.D., Lightfoot, J., Kingston, G.A. (1972) An Examination of Italian Mine Samples and Relevant Powders. University College Cardiff, Wales, UK. Report to Johnsons & Johnson September 8, 1972.
- Pooley, F.d. (1972) Report of the Examination of Rock Samples from the Vermont Mine. University College Cardiff, Wales, UK. Report to Johnson & Johnson.
- Robinson, G.R. Jr., Van Gosen, B.S., and Foley, N.K. (2006) Ultramafic-hosted talcmagnesite deposits. 2nd Forum, Geology of Industrial Minerals, Ashville, North Carolina.
- Rohl, A.N., Langer, A.M., Selikoff, I.J., Tordini, A., Klimentidis, R., Bowes, D.R., Skinner, D.L. (1976) Consumer talcums and powders: Mineral and chemical characterization. Journal of Toxicology and Environmental Health Sciences. Vol. 2, pp.255-284.
- Rubino, G.F., Gcansetti, G., Piolatto, G., Romano, C.A. (1976) Mortality Study of Talc Miners and Millers. Journal of Occupational Medicine, Vol. 18, No. 3.
- Rubino, G.F., Scansetti, G., and Piolatto, G. (1979) Mortaligy and morbidity among talc minerals and millers in Italy. Dusts and Disease, 357-363.
- Sandrone, R. and Borghi, A. (1992) Zoned garnets in the northern Dora-Maira Massif and their contribution to a reconstruction of the regional metamorphic evolution. European Journal of Mineralogy, 4, 465-474.
- Sandrone, R. and Zucchetti, S. (1988) Geology of the Italian high-quality cosmetic talc from the Pinerolo district (Western Alps). Zuffar' Days – Symposium held in Cagliari, 105-113.
- Sandrone, R., Got, D.T., Respino, D., and Zucchetti, S. (1987) Osservazioni geo-giacimentologiche sulla miniera di talco di Fontane (Val Germanasca, Alpi Cozie) [translated title = Geological and mining-geology observations concerning the talc mine at Fontane (Germanasca Valley, Cottian Alps)]. Memorie di Scienze Geologiche, 49, 175-186.
- Sandrone, R., Colombo, A., Fiora, L., Fornaro, M., Lovera, E., Tunisi, A., and Cavallo, A. (2004) Contemporary natural stones from the Italian Western Alps (Piedmont and Aosta Valley Regions). Periodico di Mineralogia, 73, 211-226.
- Thompson, B.D., Gunter, M.E., and Wilson, M.A. (2011) Amphibole asbestos soil contamination in the USA: A matter of definition. American Mineralogist, 690-693.

- United States Environmental Protection Agency (EPA) (1992) Health Assessment Document for Talc. EPA-600/8-91/217.
- Van Diver, B.B. (1987) Roadside Geology of Vermont and New Hampshire. Mountain Press Publishing Company, Missoula, Montana, pp. 230.
- Van Gosen, B.S., Lowers, H.A., Sutley, S.J., and Gent, C.A. (2004) Using the geologic setting of talc deposits as an indicator of amphibole asbestos content. *Environmental Geology*, 45, 920-939.
- Veblen, D.R. and Burnham, C.W. (1978a) New biopyriboles from Chester, Vermont: I. Descriptive mineralogy. *American Mineralogist*, 63, 1000-1009.
- Veblen, D. R., and Burnham, C.W. (1978b) New biopyriboles from Chester, Vermont: II. The crystal chemistry of jimthomsonite, clinojimthompsonite, and chesterite, and the amphibole-mica reaction. *American Mineralogist*, Vol. 63, pp. 1053-1073.
- Wang, J. and Li, Z.X., 2003. History of Neoproterozoic rift basins in South China: implications for Rodinia break-up. *Precambrian Research*, 122, 141-158.
- Wang, X.L., Zhou, J.C., Qui, J.S., Zhang, W.L., Liu, X.M., Zhang, G.L. (2006) LA-ICP-MS U-Pb zircon geochronology of the Neoproterozoic igneous rocks from Northern Guangxi, South China: Implications for tectonic evolution. *Precambrian Research*, 114, 111-130.
- Yan, D.P., Zhou M.F., Song, H.L., Wang, X.W., Malpas, J. (2003) Origin and tectonic significance of a mesozoic multi-layer over-thrust system within the Yangtze Block (South China). *Tectonophysics*, 361, 239-254.
- Zucchetti, S. (1972) Caratteri lito-mineralogici e genetici del giacimenti di talco della Val Germanasca nelle Alpi Occidentali (Italia) [translated title = Lithological, mineralogical and genetic characteristics of the Germanasca Valley talc deposits in the western Alps, Italy]. *Geologija*, 15, 263-279.